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IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

PATRICIA INGRAM, *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

If a district court excludes scientific expert testimony under the Federal Rules of Evidence pursuant to *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), is the standard of review on appeal: (1) whether the exclusion was "manifestly erroneous" (as five Circuits hold); (2) whether it was an "abuse of discretion" (as five other Circuits hold); or rather (3) whether it can withstand a "hard look" that is "more stringent" and explicitly disfavors exclusion (as the Third Circuit held here)?

LIST OF PARTIES

Petitioners in this Court are General Electric Company, National Railroad Passenger Corporation, the City of Philadelphia, Southeastern Pennsylvania Transportation Authority, Monsanto Company, American Premier Underwriters, Inc., and the Budd Company.

Respondents as parties to the proceeding in the Court of Appeals are Mabel Brown, George Burrell, Priscilla Burrell, Amber Burrell, Monica Hilton, Wallace D. Cummins, K. Louise Jones, Harvey Jones, James Lament, Christopher Brown, Jacqueline Michelle Brown, Cathlene Brown, Craig Brown, Margherita Barbetta, Mary Retta Johnson, Celeste Brown, Clemmon Brown, Cloyd Brown, Curtis Brown, John Ingram, Sr., John Ingram, Jr., Patricia Ingram, April Ingram Robinson-Ray, Mary Alice Knight, William Butler, Theresa Butler, Bryan Jackson, Allen Simpson, Donald Simpson, Karen Simpson, Marvin Simpson, Matthew Cunningham, Bessie Cunningham, and Westinghouse Electric Corporation.

LIST PURSUANT TO RULE 29.1

Petitioner General Electric Company is a publicly held New York corporation with no parent companies. Its subsidiaries, other than wholly owned subsidiaries and subsidiaries whose shares or debt securities are not publicly held, are General Electric Capital Corporation; General Electric Credit International, N.V.; Montgomery Ward & Company, Inc.; General Electric Capital Preferred Asset Corporation; CAMCO, Inc. (Canada); General Electric Capital Services, Inc.; GECC Financial Corporation (Hawaii); General Electric Capital Canada, Inc.; GNA Corporation; Mercur Bank (Austria); Imaging Financial Services, Inc.; and Dart & Kraft Leasing Corporation.

Petitioner National Railroad Passenger Corporation is a District of Columbia corporation. It has no parent companies. Its subsidiaries are Chicago Union Station and Washington Terminal Company.

Petitioner the City of Philadelphia is a Pennsylvania City of the First Class, pursuant to 53 PA. STAT. ANN. § 101.

Petitioner Southeastern Pennsylvania Transportation Authority is a Metropolitan Area Transportation Authority existing pursuant to the Pennsylvania Public Transportation Law, 74 PA. CONS. STAT. §§ 1701-1785, Act No. 1994-3, by terms of which it is a "body corporate and politic" and an "agency and instrumentality of the Commonwealth." It has no subsidiaries.

Petitioner Monsanto Company is a publicly held Delaware corporation with no parent companies. It has no subsidiaries other than wholly owned subsidiaries.

Petitioner American Premier Underwriters, Inc., formerly known as The Penn Central Corporation, is a publicly held Pennsylvania corporation with no parent companies. Its subsidiaries, other than wholly-owned subsidiaries, are Insurance (GB), Ltd.; Casualty Underwriters, Inc.; Detroit Manufacturers Railroad Company; New York & Harlem Railroad Company; Pennsylvania-Reading Seashore Lines (co-owned with the Reading Railroad Company); and Pittsburgh & Cross Creek Railroad Company (co-owned with the Norfolk & Southern Railroad Company).

Petitioner the Budd Company is a Michigan corporation and is a wholly-owned indirect subsidiary of Thyssen AG, a publicly held German corporation. The Budd Company has no subsidiaries other than wholly-owned subsidiaries. Its subsidiary Budcan Holdings, Inc. owns a less-than-78% common stock interest in Budd Canada, Inc., a publicly held Ontario, Canada corporation. The Budd Company's subsidiary Milford Fabricating Company owns a 50% common-stock interest in E.T.M.F., Inc., a Michigan corporation.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit entered in these cases August 31, 1994.

OPINIONS BELOW

The opinions of the District Court that excluded certain testimony and granted summary judgment are unreported and are reproduced in the Appendix at A. 169a.[1] The opinion of the Court of Appeals is reported at 35 F.3d 717 and is reproduced at A. 1a. The order of the Court of Appeals denying rehearing is unreported and is reproduced at A. 160a.

JURISDICTION

The judgment of the District Court was entered October 21, 1992. A. 302a.[2] The judgment of the Court of

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[1] References herein to "A." are to the Appendix filed herewith, and to "R." to the record in the joint appendix in the Court of Appeals.

[2] A separate opinion of the District Court dealing with property-damage issues that are not raised in this petition was rendered November 13, 1992.

Appeals was entered August 31, 1994. A. 1a. A timely petition for rehearing was denied October 14, 1994. A. 160a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RULES INVOLVED

Rules 104, 401, 402, 403, 701, 702 and 703 of the Federal Rules of Evidence appear in Addendum B at pp. B1-B3, *infra*.

STATEMENT

A group of plaintiffs who lived near the railroad yard at Paoli, Pennsylvania brought these actions claiming to have suffered more than fifty different illnesses as a result of exposure to PCBs (polychlorinated biphenyls) that were used as fire-retardant fluid in railroad transformers at the railroad yard. The defendants manufactured PCBs or transformers, or owned or operated the yard or the equipment used there. The cases were brought in or removed to the United States District Court for the Eastern District of Pennsylvania. The only issue presented in this petition is what standard the Court of Appeals should have applied when it reviewed the District Court's decision on admissibility of expert opinions.

A. Earlier Proceedings.

The plaintiffs, respondents here, relied on expert witnesses to establish the essential elements of their case—exposure, causation and injury. The defendants, petitioners here, challenged the admissibility of those opinions under Rules 702, 703, 402 and 403 of the Federal Rules of Evidence.

Initially, based upon deposition admissions by the plaintiffs' proposed experts, and affidavits from a panel of prominent scientists that the proffered opinions lacked any basis in science, the District Court held the expert testimony inadmissible as not meeting the standards of those Federal Rules; it then granted summary judgment for the defendants. *In re Paoli R.R. Yard PCB Litigation*, 706 F. Supp. 358 (E.D. Pa. 1988). The Third Circuit reversed on procedural grounds and remanded for

further proceedings: it held that the District Court had not adequately explained its rulings and had not allowed the plaintiffs "an adequate opportunity to present their factual and legal contentions" as to whether the opinions had scientific basis; in remanding, the Court of Appeals admonished that "the most efficient procedure that the district court can use . . . is an *in limine* hearing." *In re Paoli R.R. Yard PCB Litigation,* 916 F.2d 829, 836, 859 (3d Cir. 1990). At that stage a petition for certiorari seeking to review the procedural requirements imposed and whether the District Court's rulings had been supported by the record was denied, and the case returned to the District Court. *General Elec. Co.* v. *Knight,* No. 90-1309, 499 U.S. 961 (1991).

B. District Court Hearing and Ruling.

After remand, the District Court did hold an *in limine* hearing, so extensive that it lasted for five days. Plaintiffs offered opinions of two physicians (as to injury, causation, and alleged need for many years of "medical monitoring") and one physicist (opining as to whether levels of PCBs in the plaintiffs' blood were abnormal). Defendants presented nine scientists and physicians, both leading practitioners and professors of medicine, including heads of departments in teaching hospitals. These experts testified:

> — That the principal physician relied on by the plaintiffs was not medically qualified, would not be recognized as competent either to diagnose or to treat, and was offering opinions not based on any reliable medical methodology;
>
> — That the experts offered by the plaintiffs had not followed the methodology of science that is required before one could support the opinions they offered;
>
> — That the plaintiffs' experts had relied on data that were not data of a kind relied on by scientists for the purposes the experts sought to use them;
>
> — And that both in scientific particulars and in conclusions, the opinions being offered were not rec-

> ognizable as science, and would not be accepted as such by scientists in the relevant disciplines.

The plaintiffs presented no witnesses to support the qualifications and methodology of their experts, other than the experts themselves.

The District Court after hearing the testimony and reviewing exhibits then made findings of fact and concluded that the opinions were inadmissible. It filed detailed and comprehensive opinions as to each, citing to the hearing record and explaining the bases for each of its evidentiary rulings. A. 169a, 215a, 251a, 282a, 311a, 333a, 346a. In particular, it excluded under Rules 702, 703 and/or 403, expert opinions of:

1. A medical doctor who had not treated any patient since 1976 but had appeared as a plaintiff's or claimant's expert in 800 cases; who had concededly never failed to diagnose PCBs as the cause of whatever illness was claimed by any person claiming exposure to PCBs; and who had not even examined most of the plaintiffs as to whom these medical opinions were offered.[3] Five medical teachers and practitioners [4] testified, and the District Court

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[3] The proffered expert opinion was that exposure to PCBs had caused the plaintiffs to suffer headaches, dizziness, insomnia, memory disturbance, Parkinson's syndrome, hyperactivity, metastatic brain tumor, glaucoma, episcleritis, ringing in ears, infections, pleural thickening, obstructive lung disease, restrictive lung disease, asthma, pneumonia, respiratory distress, mitral insufficiency, aortic sclerosis, carotid stenosis, congestive heart failure, aortic insufficiency, abdominal pain, enterocolitis, nausea and vomiting, diabetes mellitus, splenomegaly, stomach cancer, hematuria and urinary infections, premature breast development, polychondritis, arthritis, neuropathy, muscular weakness, vascular insufficiency, bone abnormality, multiple skin problems in a new-born, increase in melanocytes with pigmented lesions, anemia, anisocytosis and poikilocytosis, pancytopenia, lymphocytosis, myeloproliferative changes with bone marrow hypercellularity, eosinophilia, megaloblastic maturation of erythroid, myeloid and megakaryocyte series, elevated alkaline phosphatase, elevated lactic dehydrogenase, elevated CPK and SGOT, elevated triglycerides, and elevated glucose. R. 442-45; see A. 188a-189a.

[4] They were Paul M. Roediger, M.D., Chief of General Internal Medicine and Director of Medical Education at Abington Memorial

found, that no recognizable scientific methodology could support these opinions, and that this doctor, although holding a degree, would not be granted admitting privileges by any hospital and was unqualified to treat patients or diagnose medical conditions. A. 187a. The District Court held the expert unqualified and these opinions inadmissible under Rule 702 for failure to follow any reliable scientific methodology, and alternatively under Rule 403 as misleading and likely to confuse a jury. A. 206a, 209a, 210a.[5]

Hospital, A. 175a; Jordan N. Fink, M.D., Professor of Immunology at the Medical College of Wisconsin and past President of the American Academy of Allergy and Immunology, A. 173a; James Leyden, M.D., Chief of Dermatology, University of Pennsylvania Medical School, A. 176a; Robert W. Morgan, M.D., S.M. Hyg., former Professor of Preventive Medicine and Epidemiology at the University of Toronto and Director of the Stanford Research Internal Center for Community Health Studies, A. 178a; and Michael R. Weitekamp, M.D., F.A.C.P., Chief of General Internal Medicine at Hershey Medical Center and Associate Professor of Medicine at Pennsylvania State University Medical School, A. 178a-179a.

[5] The District Court found, for example, based on the testimony of the doctors at the *in limine* hearing, that the proposed expert was ignorant of the most basic medical facts, A. 182a-187a; did not know the difference between blood serum and blood plasma, A. 180a; opined as to "antigenic damage," which cannot exist because antigens do not damage, A. 182a; was unaware of well-known differences between chloracne and common acne, A. 185a-186a; failed to order standard laboratory tests, A. 187a; did not know how to interpret the tests that were ordered (from an unaccredited laboratory), A. 181a-182a, 184a-185a, 197a; claimed expertise in toxicology without having taken a single course on that subject, A. 173a, 186a, 212a; relied on newspaper articles as scientific medical authority, A. 196a-197a; and blamed PCBs for illnesses without considering that such illnesses had well-known common causes, A. 183a, 188a-191a, 195a, 207a. See A. 204a-206a. The unrebutted testimony of the former head of the American Academy of Allergy and Immunology was that the proposed expert lacked basic medical knowledge that "should be right in the forefront of knowledge of any internist, any resident, any medical student," and that as for the medical methodology employed, "I couldn't find any." A. 189a. Others confirmed that lack of medical knowledge and scientific methodology. A. 189a, 190a, 206a.

2. Another medical doctor who sought to present the opinion that "even one molecule" of PCBs was sufficient to cause illness—even though it was undisputed that small levels of PCBs are present in nearly everyone. He opined that all the plaintiffs required at least 25 years of "medical monitoring," A. 261a, offering this opinion although he had never met any of the plaintiffs, had never seen their medical records, and had never ordered any standard tests of them. A. 255a, 261a. Based upon testimony of three physicians "that the methodology used . . . is neither standard nor reliable," A. 266a-267a, because "Dr. DiGregorio merely assumes that all of the Plaintiffs are extremely sensitive to PCBs, such that even the slightest exposure will cause serious injuries," A. 262a, 264a, the District Court found that this opinion lacked any basis in known medical methodology, and excluded it under Rules 702 and 703. A. 259a, 269a-271a. It also excluded under Rule 702 the "medical monitoring" opinion, finding that "Dr. DiGregorio's methodology in rendering this opinion is non-existent, and therefore completely unreliable." A. 278a.

3. A physicist who would opine, contrary to nationally accepted data, that the plaintiffs had abnormally high levels of PCBs in their blood. Actual blood tests established that the level of PCBs in the plaintiffs' blood when measured did not exceed the "background" levels regarded by accredited medical laboratories as normal throughout the United States. But the plaintiffs' proposed expert said that the accepted background levels were incorrect, relying on his own unique extrapolations from a 1970's survey of cadaver fat (not blood) samples, which a leading toxicologist testified, and the District Court found, were neither "accurate" nor "reliable" for such a purpose. A. 244a, 248a. The District Court excluded this opinion under Rules 702 and 703. A. 249a.

Because these opinions were necessary to support essential elements of the plaintiffs' claims, the District Court then granted summary judgment, citing *Celotex Corp.* v.

Catrett, 477 U.S. 317 (1986). A. 299a, 303. The plaintiffs appealed, arguing that the District Court's rulings based on the five-day hearing violated the Federal Rules of Evidence.

C. Court of Appeals Review and Reversal.

The portion of the Court of Appeals' opinion to which this petition is directed occupies only three pages, A. 51a-53a, also reprinted in Addendum A, *infra* at pp. A5-A8. On appeal the defendants cited many authorities holding that rulings of a district court as to admissibility of expert opinions may be reversed only if "manifestly erroneous." *Salem* v. *United States Lines Co.,* 370 U.S. 31, 35 (1962). But the Court of Appeals in an opinion by Judge Becker ruled that after this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.,* 113 S. Ct. 2786 (1993), "there is a significant risk that district judges will set the threshold too high." A. 52a, *infra* p. A7.

> "[G]iven the enormous power of the district court to foreclose submission of a party's case to a jury on the basis of a threshold determination of nonreliability of opinion evidence, we conclude that the review requires a 'hard look' to insure that the district court's exercise of discretion was sound and that it correctly applied the several *Daubert* factors."

A. 15a, *infra* p. A3.

Therefore, the Court of Appeals held, hereafter when district courts exclude expert testimony and summary judgment will result, the Third Circuit in reviewing *Daubert* rulings will use a "heightened abuse of discretion review," A. 51a, *infra* p. A6, applying "a hard look at (more stringent review of) the district court's exercise of discretion." A. 52a, *infra* p. A6.

> "[W]hen the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a 'hard look' (more stringent review, cf. *Brody* v. *Spang,* 957 F.2d [1108] at 1115 [(3d Cir. 1992)]) to determine if a district court has

abused its discretion in excluding evidence as unreliable."

A. 53a, *infra* p. A8 (footnote omitted).

The Court of Appeals then applied its new "more stringent" "hard look" standard to reverse many of the District Court's admissibility rulings:

1. The Court of Appeals reversed the District Court's findings that the principal medical witness lacked the expertise required by Rule 702. Rejecting the District Court's reliance on unchallenged testimony of the five prominent physicians that the witness was unqualified to practice medicine or diagnose, the Court of Appeals held that it was sufficient that the witness long ago had once been on the consulting staff of a hospital, had published articles, and had served on committees—even though the Court of Appeals acknowledged the witness to be "arguably a relatively poor clinician," "less than fully credible" and "the number of mistakes she made was quite significant," and referred to what it called "Dr. Sherman's somewhat dubious expertise." A. 60a, 61a, 85a. Contrary to the testimony of the eminent physicians at the hearing, which the District Court had found credible and convincing, the Court of Appeals concluded that "many of Dr. Sherman's mistakes seem minor." A. 61a.[6]

2. The Court of Appeals also rejected the District Court's crediting of the experts who testified as to the diagnostic and analytical process of medical science, and reversed the District Court's Rule 702 finding as to reliable methodology. The District Court based on the record had concluded that it simply is not a "reliable methodology" to opine that PCBs had caused ailments which by no

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[6] For example, in the words of the Court of Appeals:

"Dr. Fink concluded that these gaps in knowledge were 'major deficits. They—these items should be right in the forefront of knowledge of any internist, any resident, any medical student.' The district court concluded that these 'major deficits' removed Dr. Sherman from the category of expert.

"We disagree." A. 60a.

known medical theory they were capable of causing. A. 206a, 209a. Nevertheless, the Court of Appeals held that as to plaintiffs examined, "Dr. Sherman's scientific methodology was reliable," A. 17a, and that "the district court should have presumed that her testimony was reliable." A. 85a.

3. The Court of Appeals also reversed the District Court's ruling, A. 210a-211a, that had alternatively excluded these opinions under Rule 403.[7] "The 403 ruling will be reversed," the Court of Appeals said, because "[w]e fail to see what characteristics of Dr. Sherman's testimony would make it the subject of the type of 403 balance necessary for its exclusion." A. 97a.

4. The Court of Appeals went on to reverse the District Court's findings that the other physician's opinion—that exposure to "one molecule" of PCBs was sufficient to require compensation for at least 25 years of medical tests for patients whom he had never examined—was not based on recognizable medical methodology or any known medical theory. The Court of Appeals ruled that "[w]e agree with plaintiffs that Dr. DiGregorio could reliably testify as to a patient's future risks without examining the patients," A. 141a-142a, even though it acknowledged that his assumption was that this need for "medical monitoring" tests "would be true of anyone exposed to even one molecule of PCBs." A. 140a.

5. Although the District Court had excluded as unreliable the data and methodology used by the plaintiffs' exposure expert, who had revised the established national background level of PCBs, the Court of Appeals after reading the hearing record concluded:

> "after taking a hard look, the court's conclusion that the (converted) fat data is not reasonably relied upon does not survive the foregoing analysis. Aided by the preference for admissibility of such evidence

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[7] Rule 403 authorizes the trial court to exclude testimony whose "probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury."

under the rules, the NHATS data is reliable enough . . . and it passes *Daubert* muster." A. 106a.[8]

6. The Court of Appeals also held that the District Court could not rely on the hearing testimony to conclude under Rules 402, 403, 702 and 703, A. 290a-291a, that animal experiments, although sometimes useful in identifying risk, were unreliable to establish that PCBs could cause particular human ailments without confirmation from actual human epidemiological data. Although the Court of Appeals acknowledged that several other courts had reached exactly the same conclusion in this context as the District Court,[9] it nevertheless disagreed—and, under its new "more stringent" standard of *Daubert* review, reversed. A. 117a-121a.

Having held that all these admissibility rulings by the District Court failed to satisfy the "hard look" standard of review for *Daubert* rulings, the Court of Appeals reversed the summary judgment as to all claims for medical monitoring whether or not the plaintiffs had ever been examined, and also reversed as to all personal-injury claims except those in which the plaintiffs had not been examined by the proffered experts. A. 18a-19a. Judge Roth, concurring, disagreed with the portion of the majority's holding, A. 41a, that "[a] judge frequently should find an expert's methodology helpful even when the judge thinks that the expert's technique has flaws sufficient to render the conclusions inaccurate." A. 159a. Rehearing was denied. A. 160a.

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[8] Reversing the District Court's finding after the hearing, the Court of Appeals held that "[w]e are satisfied that Dr. Nisbet's calculation of background blood levels from National Human Adipose Tissue Survey ('NHATS') fat data was based on a reliable methodology." A. 18a.

[9] *E.g.*, *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992); *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823, 839 (D.C. Cir. 1988); *Lynch* v. *Merrell-National Labs.*, 830 F.2d 1190, 1194 (1st Cir. 1987).

REASONS FOR GRANTING THE WRIT

The familiar starting point in any federal appeal is the standard of review by which the court of appeals is to judge the district court's ruling. Last year in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), this Court held that district judges are to exercise "a gatekeeping role" as to admissibility of scientific opinions. 113 S. Ct. at 2798. But this Court did not address the standard by which such rulings are to be reviewed on appeal. The courts of appeals have been left to determine what their standard of review of evidentiary rulings after *Daubert* should be. Nearly all have now done so, and they have reached differing answers.

Four Circuits now have held that the standard of review continues to be, as this Court held it was before *Daubert*, that a district court's rulings on admissibility of expert opinions will be affirmed unless they are "manifestly erroneous;" a fifth Circuit applies that standard in most cases. But five other Circuits review under a simple "abuse of discretion" standard, while sometimes emphasizing the trial judge's "broad discretion."

The Third Circuit in this case, however, has adopted an extreme standard unlike any of the others, that is far more hostile to district court exclusions under *Daubert*. In the Third Circuit, district court admissibility rulings, if they exclude expert testimony, are now subjected to a "hard look," that is "more stringent" and that explicitly disfavors exclusion. Were it not for the Court of Appeals' adoption of that new standard, the detailed and meticulous findings and rulings of admissibility by the District Court here could not have been reversed. This departure, which puts the important Third Circuit at odds with the law applied in ten other Circuits, can be settled only by this Court.[10]

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[10] The Third Circuit's standard has some support from one commentator, who argued that *Daubert* should be read as establishing a new rule that "[a]ppellate courts need not defer to the trial court's reliability determination." Giannelli, *Daubert: Interpreting*

I. THE THIRD CIRCUIT'S "HARD LOOK" STANDARD OF REVIEW IS IN CONFLICT WITH THE STANDARD USED IN TEN OTHER CIRCUITS.

The standard of review to be applied to trial court rulings on admissibility of expert opinions comes up so often that in the less than eighteen months since *Daubert* was decided, nearly all the Circuits now have addressed it.[11]

1. Five Circuits apply a highly deferential "manifestly erroneous" standard of review.

— The First Circuit thus holds that "[b]ecause gauging an expert witness's usefulness is almost always a case-specific inquiry, the law affords trial judges substantial discretion in connection with the admission or exclusion of opinion evidence," and "a trial judge's rulings in this sphere should be upheld 'unless manifestly erroneous.'" *United States* v. *Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993), *quoting in part Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962).

— The Second Circuit agrees that "[a] decision to allow expert testimony is within the broad discretion of the trial judge and 'is to be sustained on appeal unless manifestly erroneous.'" *United States* v. *Daccarett*, 6 F.3d 37, 58 (2d Cir. 1993), *cert. denied sub nom. Creaciones Viviana Ltda.* v. *United States*, 114 S. Ct. 1294, 1295, 1538 (1994); *accord, United States* v. *Locascio*, 6 F.3d 924, 936 (2d Cir. 1993) (district court's ruling will be affirmed unless "manifestly erroneous"), *cert. denied sub nom. Gotti* v. *United States*, 114 S. Ct. 1646 (1994); *United States* v. *Amuso*, 21 F.3d 1251, 1263 (2d Cir.) (decision under Rule 702 whether to admit expert testimony "will be disturbed only if it was manifestly erroneous"), *cert. denied*, 115 S. Ct. 326 (1994).

— The Fifth Circuit holds that *Daubert* leaves unchanged the rule that "[a] trial court's ruling re-

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the Federal Rules of Evidence, 15 CARDOZO L. REV. 1999, 2011 (1994).

[11] No pertinent decision of the Eleventh or Federal Circuits has yet been reported.

garding admissibility of expert testimony is protected by an ambit of discretion and must be sustained unless manifestly erroneous." *Rosado* v. *Deters*, 5 F.3d 119, 124 (5th Cir. 1993), *quoting Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1280 (1992).

— The Sixth Circuit agrees that "[t]he scope of this discretion [of the district court] has been broadly construed, and the trial court's actions are to be sustained 'unless manifestly erroneous.'" *United States* v. *Bonds*, 12 F.3d 540, 554 (6th Cir. 1993), *quoting in part United States* v. *Green*, 548 F.2d 1261, 1268 (6th Cir. 1977); *accord, Cantrell* v. *GAF Corp.*, 999 F.2d 1007, 1014 (6th Cir. 1993) (same).

— The Seventh Circuit, in a case decided a few days before *Daubert*, reiterated that a trial court's admissibility decision "will generally not be disturbed unless it is manifestly erroneous," but then added that "we will review *de novo* the reliability of the scientific facts, data, and techniques utilized" by the witness. *Cella* v. *United States*, 998 F.2d 418, 423 (7th Cir. 1993) (affirming exclusion by district court). Then after *Daubert*, *in Mars* v. *United States*, 25 F.3d 1383 (7th Cir. 1994), noting that "[t]he issue that we have been discussing is important," it explained that the kind of *de novo* review referred to in its *Cella* decision would be confined to cases where the issue was whether an entire class of scientific evidence was inadmissible. 25 F.3d at 1384. It also has emphasized that "[i]f the judge is not persuaded that the so-called expert has genuine knowledge that can be genuinely helpful to the jury, he should not let him testify." *Wilson* v. *City of Chicago*, 6 F.3d 1233, 1238-39 (7th Cir. 1993), *cert. denied*, 114 S. Ct. 1844 (1994).

2. Instead of the "manifestly erroneous" standard of deference, five Circuits follow a simple abuse-of-discretion standard of review:

— The Fourth Circuit holds that rulings under *Daubert* are "committed, as are most questions of admissibility of evidence, to the discretion of the district courts." *United States* v. *Bynum*, 3 F.3d 769, 773 (4th Cir. 1993), *cert. denied*, 114 S. Ct. 1105 (1994).

— The Eighth Circuit in reviewing rulings under *Daubert* also follows the standard of abuse of discretion. *United States* v. *Martinez*, 3 F.3d 1191, 1198 (8th Cir. 1993), *cert. denied*, 114 S. Ct. 734 (1994); see also *Sorensen* v. *Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994) (affirming exclusion because "the hypotheses presented by plaintiffs' experts follow no scientific principles").

— The Ninth Circuit also applies what it describes as an "abuse of discretion" standard. *United States* v. *Jones*, 24 F.3d 1177, 1179 (9th Cir. 1994); *United States* v. *Rincon*, 28 F.3d 921, 923 (9th Cir. 1994) (adhering to "abuse of discretion" standard after remand by this Court, 114 S. Ct. 41 (1993), for reconsideration in light of *Daubert*), *cert. denied*, 63 U.S.L. WEEK 3421 (U.S. Nov. 29, 1994).

— The Tenth Circuit holds that "[t]he trial court's decision to admit expert testimony is reviewable for abuse of discretion." *United States* v. *Markum*, 4 F.3d 891, 895 (10th Cir. 1993); *accord*, *United States* v. *Muldrow*, 19 F.3d 1332, 1337 (10th Cir.), *cert. denied*, 115 S. Ct. 175 (1994); *United States* v. *Davis*, 1994 U.S. App. Lexis 31992 (10th Cir. Nov. 15, 1994) (district court's admissibility ruling "will be disturbed only for a clear abuse of discretion").

— The District of Columbia Circuit similarly reverses only for abuse of discretion, although it emphasizes that trial courts in ruling on admissibility of expert opinions are to be allowed "broad discretion." *Joy* v. *Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567 (D.C. Cir. 1993).

3. Finally, in the present case the Third Circuit, through a judge often cited in federal evidence matters,[12] uniquely has announced a standard of "more stringent review" and "hard look" for appellate review of district court admissibility rulings under Rules 702, 703 and 403—if they exclude—and has explicitly stated that this new standard is intended to disfavor district courts' excluding expert opinion testimony. Thus, instead of allowing the trial court that heard the testimony the benefit of affirmance unless "manifestly erroneous," or according at least an abuse-of-discretion deference to the trial court, the Third Circuit has gone far in the opposite direction. Its decision to subject trial judges' exclusions of scientific opinions to a "hard look" is not to be found in *Daubert,* nor in the Federal Rules of Evidence, nor in the decisions of any other Circuit.

II. THE THIRD CIRCUIT'S STANDARD IS IN CONFLICT WITH THIS COURT'S DECISIONS IN *DAUBERT* v. *MERRELL DOW PHARMACEUTICALS* AND *SALEM* v. *UNITED STATES LINES.*

Prior to its ruling in *Daubert* last year, and prior to the adoption of the Federal Rules of Evidence, this Court had consistently ruled that

> "the trial judge has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous."

Salem v. *United States Lines Co.*, 370 U.S. 31, 35 (1962). That standard of appellate review was first announced by this Court in *Spring Co.* v. *Edgar*, 99 U.S. 645, 658 (1879):

> "Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous."

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[12] Judge Becker's writings on evidence were cited by this Court in *Daubert,* 113 S. Ct. at 2793 n.4 and 2796.

Accordingly, the Circuits prior to *Daubert* generally followed a "manifestly erroneous" standard in reviewing district court rulings on admissibility of expert opinion testimony.[13]

Nothing in *Daubert* v. *Merrell Dow Pharmaceuticals* gives any hint that the rule of *Spring Co.* and *Salem* is now to be changed, so as to impose a tighter appellate review on trial judges who exclude expert opinions—a review explicitly disfavoring exclusion. On the contrary, *Daubert* in rejecting the mechanical rule of *Frye* v. *United States,* 293 Fed. 1013 (D.C. Cir. 1923), emphasized that trial courts in admissibility determinations under Rule 104(a) should be conscious of their duty to enforce Rules 702, 703 and 403, so as to make sure that opinions being presented to a jury are adequately grounded in science.[14]

The concern of *Daubert* was not, as the Third Circuit believed here, that courts of appeals should clamp down more on trial judges—particularly when, as here, the trial court has not merely listened to lawyers' arguments, but has actually heard testimony from prominent teachers and practitioners in the relevant scientific disciplines at extensive *in limine* hearings. Nor, certainly, did *Daubert* mean that more testimony lacking scientific foundation should be allowed in evidence. The emphasis of *Daubert* was exactly in the opposite direction: that trial courts should follow fair procedures and weigh appropriate fac-

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[13] *E.g., United States* v. *Tutino,* 883 F.2d 1125, 1134 (2d Cir. 1989), *cert. denied,* 493 U.S. 1081 (1990); *United States* v. *MacDonald,* 688 F.2d 224, 227-28 (4th Cir. 1982), *cert. denied,* 459 U.S. 1103 (1983); *Slaughter* v. *Southern Talc Co.,* 919 F.2d 304, 307 (5th Cir. 1990); *Perkins* v. *Volkswagen of America, Inc.,* 596 F.2d 681, 682 (5th Cir. 1979); *Apponi* v. *Sunshine Biscuits, Inc.,* 809 F.2d 1210, 1218 (6th Cir.), *cert. denied,* 484 U.S. 820 (1987); *United States* v. *Lundy,* 809 F.2d 392, 394 (7th Cir. 1987); *Hull* v. *Merck & Co.,* 758 F.2d 1474, 1477 (11th Cir. 1985); *Coleman* v. *Parkline Corp.,* 844 F.2d 863, 865-66 (D.C. Cir. 1988); *Milmark Services, Inc.* v. *United States,* 731 F.2d 855, 860 (Fed. Cir. 1984).

[14] *E.g., Daubert,* 113 S. Ct. at 2796: "We are confident that federal judges possess the capacity to undertake this review."

tors, but then should not ignore their "gatekeeping" responsibility, 113 S. Ct. at 2798, in expert evidentiary matters under the Federal Rules. *Daubert* implies more, not less, deference to the district courts. *Daubert* certainly gave no hint that appellate review of admissibility rulings should now become more demanding than the standard previously prescribed by this Court, which most courts of appeals were already applying: whether the trial court's ruling was "manifestly erroneous." And *Daubert* suggested no one-way bias in review—friendly to rulings allowing expert opinions, but hostile to district court rulings that exclude "junk science."

What the District Court did here satisfied, indeed far exceeded, every aspect of its duties prescribed in *Daubert*. The Court of Appeals could not and did not fault either the procedure—which included five days of hearings—nor the standards the District Court applied. Instead, the Third Circuit under its new "hard look" standard simply conducted a virtual *de novo* review that explicitly disfavored exclusion, and substituted its own judgment for that of the District Court (which had heard the testimony) as to whether the experts were qualified and the opinions based in science. Moreover, contrary to *Daubert*'s requirement of an evenhanded screening to protect juries from unscientific opinions, the Third Circuit says its more demanding standard of review is designed to be result-oriented: it applies when district courts exclude opinions, but not when they allow them.

III. THE ISSUE IS IMPORTANT.

It does not require the Seventh Circuit's observation that "[t]he issue that we have been discussing is important," *Mars* v. *United States, supra,* 25 F.3d at 1384, to recognize that the issue of standard of review for rulings under *Daubert* pervades federal litigation. The ubiquity of expert testimony in modern federal cases, both civil and criminal, and the very reason for adopting the Federal Rules of Evidence—to make evidentiary standards consistent throughout all federal courts—were recognized by

this Court when it granted review and decided *Daubert*.[15] It is not appropriate for the Third Circuit now to establish at the appellate level a far less deferential standard of review, that applies the Federal Rules of Evidence in a way wholly at variance with other Circuits.[16]

No aspect of any federal appeal is more important than the first question every court of appeals must ask: what is our standard of review? With evidentiary rulings on expert testimony occurring constantly in federal district courts, and regularly being appealed, the answer to that opening question should be the same in the federal courts of appeals throughout the country.[17]

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[15] "We granted certiorari . . . in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony." 113 S. Ct. at 2792.

[16] Several commentators have noted the need to settle what standard of appellate review is to be applied after *Daubert*. See Faigman, *et al., Check Your Crystal Ball at the Courthouse Door, Please*, 15 CARDOZO L. REV. 1799, 1820 (1994) ("[t]he *Daubert* court did not specify the standard appellate courts should use when reviewing a trial court's conclusions about the validity of proffered science"); Note, *Daubert v. Merrell Dow Pharmaceuticals: Pushing the Limits of Scientific Reliability*, 47 VAND. L. REV. 1175, 1196 (1994) ("[a]nother issue unresolved by *Daubert* concerns the standard of review of trial judges' decisions about admissibility made pursuant to *Daubert*'s new, flexible inquiry"); Giannelli, *supra* n.10.

[17] The importance of uniformity in standards of appellate review is underscored by this Court's recent grants of certiorari in No. 94-562, *Wilton* v. *Seven Falls Co.*, 63 U.S.L. WEEK 3420 (*cert. granted* Nov. 28, 1994) (split in the Circuits as to the standard of appellate review for district-court abstention rulings), and No. 94-560, *First Options of Chicago, Inc.* v. *Kaplan*, 63 U.S.L. WEEK 3436 (*cert. granted* Dec. 5, 1994) (split in Circuits as to the standard of appellate review for district-court rulings on arbitration awards).

CONCLUSION

For the reasons stated, certiorari should be granted.

Respectfully submitted,

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ADDENDUM A

Filed August 31, 1994

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 92-1995, 92-1997, 92-1999, 92-2000, 92-2001,
92-2002, 92-2003, 92-2004, 92-2005, 92-2006, 92-2007,
92-2008, 92-2009, 92-2010, 92-2011, 92-2014,
and 92-2016

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

* * * *

On Appeal From the United States District Court
For the Eastern District of Pennsylvania

Argued: October 26, 1993

Before: BECKER, ROTH, and LEWIS, *Circuit Judges.*

(Filed August 31, 1994)

[As Amended October 17, 1994]

OPINION OF THE COURT

BECKER, *Circuit Judge.*

I. INTRODUCTION

The plaintiffs in this toxic tort case have lived for many years in the vicinity of the Paoli Railyard, a railcar maintetenance facility at which polychlorinated biphenyls (PCBs) were used in profusion for over a quarter century. They have sued to recover damages for a variety of physical ailments and for property damage against the corporations that have maintained the railyard and that sold the PCBs.

This appeal is from the district court's second grant of summary judgment for the defendants. In *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990) ("*Paoli I*"), *cert. denied*, 499 U.S. 961, 111 S. Ct. 1584 (1991), we reversed the grant of summary judgment for defendants and remanded for further proceedings. We did so because the foundation of the summary judgment—the exclusion of virtually all the plaintiffs' expert opinion pursuant to Federal Rules of Evidence 702, 703 and 403—was undermined by (1) the failure of the district court to permit sufficient development of the record upon which a determination to exclude expert evidence might be based, and (2) the district court's failure to make findings, grounded on Fed. R. Evid. 702 or 703, setting forth the basis of its decision.

On remand the district court conducted five days of *in limine* hearings, receiving extensive evidence about the scientific reliability of plaintiffs' expert opinions. It then filed extensive opinions (totalling 330 pages) setting forth not only findings of fact but also its reasons for again excluding the vast bulk of plaintiffs' expert evidence. This appeal followed.

Resolution of the appeal requires that we address myriad issues of procedure, evidence, and substantive law. Primarily, however, we must consider the voluminous record concerning expert opinion and, applying Fed. R. Evid. 702 and the standard enunciated by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), decide whether the district court

erred in again excluding the opinions of plaintiffs' experts in connection with its summary judgment determination. *Daubert* requires the district court to act as "gatekeeper" and to assure that the scientific methodology upon which the expert opinion is founded is reliable, i.e., that the expert's conclusion is based on good grounds (the methods and principles of science). We also must deal with Fed. R. Evid. 703 because the district court's exclusion of expert testimony rests, in part, on its conclusion that some of the hearsay evidence upon which the experts relied is not of a kind usually relied on by experts in the field. In this regard we conclude that the precept announced in *In Re: Japanese Electronics Products Antitrust Litigation,* 723 F.2d 238 (3d Cir. 1983), *rev'd on other grounds sub nom., Matsushita Electrical Industrial Co. v. Zenith Radio Corp.,* 475 U.S. 574, 106 S. Ct. 1348 (1986), that the principal arbiters of the reasonableness of reliance upon inadmissible evidence are the experts and not the trial judge, does not survive *Daubert.*

Preliminary to an application of Rules 702-703 to the evidentiary rulings at issue, we must address the question of the proper scope of review. Although review of the district court's fact findings that undergird its rulings on the admissibility of expert opinion is deferential, given the enormous power of the district court to foreclose submission of a party's case to a jury on the basis of a threshold determination of nonreliability of opinion evidence, we conclude that the review requires a "hard look" to insure that the district court's exercise of discretion was sound and that it correctly applied the several *Daubert* factors. Then to the extent that any of the expert opinion survives, we must determine whether the plaintiffs can avoid summary judgment on any of the claims to which the surviving opinion pertains.

For the most part we affirm the rulings and the judgment of the district court. However, we also reverse in part, and remand some claims for trial. In summary we rule as follows:

* * * *

3. We reverse the district court's exclusion of the opinion of Dr. Janette D. Sherman insofar as it was grounded on the conclusion that she was an unqualified expert. However, we affirm the district court's holding that she could not rely on immunological tests from an unaccredited laboratory. We also affirm the district court's exclusion of the opinions of Dr. Sherman as to causation of plaintiffs' present injuries with respect to those plaintiffs whom she did not examine and whose medical history she did not take. We believe that, in the absence of employment of the standard techniques of differential diagnosis, and in the absence of any good explanation justifying her conclusion in the light of possible alternative causes of plaintiffs' injuries, Dr. Sherman's methodology as to those plaintiffs was not reliable, as the district court found.

* * * *

5. We reverse the district court's exclusion from evidence of the opinions of Dr. Sherman with respect to most of the injuries of Bessie Cunningham and Amber Burrell, whom she actually examined and whose medical histories she took. In light of: (1) Dr. Sherman's employment of the standard techniques of differential diagnosis with respect to those plaintiffs, and (2) defendants' failure to point to possible alternative causes of their injuries which Dr. Sherman failed to consider, we are satisfied that, with respect to them, Dr. Sherman's scientific methodology was reliable and that the district court's exclusion of her opinion represented an impermissible jury-like determination that it preferred the defendants' experts' opinion to that of Dr. Sherman.

* * * *

7. We reverse the district court's exclusion of the remainder of Dr. Nisbet's opinion, including his conclusion that plaintiffs had PCBs in their blood at levels above the background PCB levels in the general population. We are satisfied that Dr. Nisbet's calculation of background blood levels from National Human Adipose Tissue Survey ("NHATS") fat data was based on a reliable

methodology, and that the NHATS data was a type of data reasonably relied on by experts.

8. We reverse the district court's exclusion of animal studies. Where, as here, these studies were supported by some epidemiological data and had been used by EPA to conclude that PCBs were a probable human carcinogen, plaintiffs' experts had good grounds for determining that they "fit" a conclusion regarding human causation.

* * * *

10. We reverse the grant of summary judgment with respect to those personal injury plaintiffs for whom Dr. Sherman's testimony is admissible, concluding that they have demonstrated the existence of a genuine issue of material fact as to whether defendants exposed them to PCBs which caused their present injuries.

11. We reverse the grant of summary judgment with respect to the medical monitoring claims. Although recent changes in Pennsylvania law have interred plaintiffs' increased risk claims, we still believe that the Pennsylvania Supreme Court would recognize the plaintiffs' medical monitoring claims, and are satisfied that Dr. Sherman's testimony as to the plaintiffs' future risk is sufficient to get them over the summary judgment threshold.

* * * *

C. *Standard of Review*

A district court's ruling on admissibility of evidence is reviewed for abuse of discretion, "but to the extent the district court's ruling turns on an interpretation of a Federal Rule of Evidence our review is plenary." *De Luca*, 911 F.2d at 944. The threshold rule is, of course, one of deference. However:

> the justifications for committing decisions to the discretion of the court are not uniform, and may vary with the specific type of decisions. Although the standard of review in such instances is generally

> framed as "abuse of discretion," in fact the scope of review will be directly related to the reason why that category or type of decision is committed to the trial court's discretion in the first instance.

United States v. Criden, 648 F.2d 814, 817 (3d Cir. 1981). In several other areas, we have applied a heightened abuse of discretion review. *See, e.g., Brody v. Spang*, 957 F.2d 1108, 1115 (3d Cir. 1992) ("We review a denial of a motion to intervene as of right for abuse of discretion, although this review is 'more stringent' than the abuse of discretion review we apply to a denial of a motion for permissive intervention"); *Harris v. Pernsley*, 820 F.2d 592, 597 (3d Cir.), *cert. denied*, 484 U.S. 947, 108 S. Ct. 336 (1987). Under the *Harris* standard, a denial of intervention as of right should be reversed if the district court applied an improper legal standard or reached a decision that we are confident is incorrect." (internal quotation omitted)); *United States v. Miele*, 589 F.2d 659, 667 (3d Cir. 1993) (looking rigorously to see whether the district court had closely scrutinized drug quantity when the court based its decision on the statements of an addict-informant); *cf. Malchman v. Davis*, 706 F.2d 426, 434 (2d Cir. 1983) (holding that while a court of appeals normally reviews a class action settlement for abuse of discretion "this principle [of deference] applies with less force when, as here, settlement of a class action has been negotiated before the class has been certified.").

While evidentiary rulings are generally subject to a particularly high level of deference because the trial court has a superior vantage point to assess the evidence, *see Criden*, 648 F.2d at 818, evaluating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses and thus is often not significantly more difficult on a cold record. Moreover, here there are factors that counsel in favor of a hard look at (more stringent review of) the district court's exercise of discretion. For example, be-

cause the reliability standard of Rule 702 and 703 is somewhat amorphous, there is a significant risk that district judges will set the threshold too high and will in fact force plaintiffs to prove their case twice. Reducing this risk is particularly important because the Federal Rules of Evidence display a preference for admissibility.[20] *See Daubert*, 113 S. Ct. at 2794.

Factors like those just discussed influence the scope of our review of a district court's discretion. For example, where rules display a preference for a particular outcome, our review of decisions under those rules is sometimes more searching. *See United States v. Pennsylvania Department of Envir't Resources*, 923 F.2d 1071, 1074 (3d Cir. 1991) ("[T]he traditional discretion of the federal courts to decide whether to hear declaratory judgment cases is not limited by *Colorado River* and *Moses H. Cone*, but will be subject to the liberal interpretation to be accorded the Declaratory Judgment Act. Given our correspondingly enlarged scope of review . . ., the district court's declination to exercise jurisdiction . . . is not consistent with a sound exercise of judicial discretion." (internal quotation omitted)). Moreover, the likelihood of finding an abuse of discretion is affected by the importance of the district court's decision to the outcome of the case and the effect it will have on important rights. *See Maroquin-Manriquez v. Immigration and Naturalization Service*, 699 F.2d 129, 134 (3d Cir. 1983) (abuse of discretion will only be found in discovery if there has been interference with a substantial right or fundamental unfairness at the trial has resulted.); *cf. Mathews v. Eldridge*, 424 U.S. 319, 334, 96 S. Ct. 893, 902 (1976) (the procedural safeguards required by due process increase as the importance of the decision being made increases).

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[20] Indeed, a similar gloss may be gleaned from the Seventh Amendment's guarantee of a right to a jury trial when a party with a legal claim demands one.

We acknowledge that there is arguably a tension between the substantial deference normally accorded to rulings where the trial court has a superior vantage point and the preference for admissibility of the Federal Rules of Evidence. We resolve any such tension by holding that when the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a "hard look" (more stringent review, *cf. Brody v. Spang*, 957 F.2d at 1115) to determine if a district court has abused its discretion in excluding evidence as unreliable.[21]

* * * *

[21] Of course, it remains true that if the scintilla of evidence presented is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, *see* Fed. R. Civ. P. 50(a), and likewise to grant summary judgment, Fed. R. Civ. P. 56.

ADDENDUM B

Federal Rules of Evidence

Rule 104

Preliminary Questions

(a) Questions of Admissibility Generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) Testimony by accused. The accused does not, by testifying upon a preliminary matter, become subject to cross-examination as to other issues in the case.

(e) Weight and credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

Rule 401

Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402

Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403

Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 701

Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.

Rule 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

B3

Rule 703

Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Supreme Court, U.S.
FILED

No. 94 1070 DEC 16 1994

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

PATRICIA INGRAM, *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

(PART I—OPINION OF COURT OF APPEALS)

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APPENDIX I

Filed August 31, 1994

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 92-1995

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MABEL BROWN, Individually and on
behalf of all others similarly situated

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION
AUTHORITY ("SEPTA"); NATIONAL RAILROAD
PASSENGER CORPORATION ("AMTRAK"); AND
CONSOLIDATED RAIL CORPORATION
("CONRAIL")

v.

UNITED STATES OF AMERICA;
ROY F. WESTON, INC.; and
OH MATERIALS COMPANY; and
GENERAL ELECTRIC COMPANY; and
THE BUDD COMPANY; and
WESTINGHOUSE ELECTRIC CORPORATION;
MONSANTO CO.;
PENN CENTRAL CORPORATION
Mabel Brown, Appellant

(D.C. Civ. No. 86-02229)

No. 92-1997

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

WALLACE DARRYL CUMMINS

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA"); and
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION, ("CONRAIL")

v.

UNITED STATES OF AMERICA; and
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
MONSANTO COMPANY
Wallace D. Cummins, Appellant

(D.C. Civ. No. 86-02669)

No. 92-1999

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

K. LOUISE JONES, ADMINISTRATRIX OF THE ESTATE OF HARVEY N. JONES, JR., DECEASED AND
K. LOUISE JONES AS PERSONAL REPRESENTATIVE OF HARVEY N. JONES, JR., AND K. LOUISE JONES IN HER OWN RIGHT

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK")
CONSOLIDATED RAIL CORPORATION, ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
MONSANTO COMPANY;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY; AND
WESTINGHOUSE ELECTRIC CORPORATION
K. Louise Jones and
Harvey Jones, Appellants

(D.C. Civ. No. 86-05277)

No. 92-2000

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

JAMES LAMENT, individually and on behalf of all others similarly situated

v.

SEPTA; AMTRAK and CONRAIL;

v.

PENN CENTRAL CORPORATION;
UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
MONSANTO CO.;
GENERAL ELECTRIC CO.;
BUDD CO., AND
WESTINGHOUSE ELECTRIC CORPORATION
James Lament, Appellant

(D.C. Civ. No. 86-05886)

No. 92-2001

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CHRISTOPHER S. BROWN;
JACQUELINE M. BROWN, h/w

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION;
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

PENN CENTRAL CORPORATION;
UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION

Christopher Brown and Jacqueline Michelle Brown, Appellants

(D.C. Civ. No. 86-07414)

No. 92-2002

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CATHLENE BROWN,

Appellant

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK");
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION

v.

PENN CENTRAL CORPORATION

(D.C. Civ. No. 86-07415)

No. 92-2003

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CRAIG A. BROWN AND
CATHERINE D. BROWN h/w

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
PENN CENTRAL CORPORATION; AND
CITY OF PHILADELPHIA;
GENERAL ELECTRIC CO.;
THE BUDD CO.; AND
WESTINGHOUSE ELECTRIC CORP.
Craig Brown, Appellant

(D.C. Civ. No. 86-07416)

No. 92-2004

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MARGHERITA BARBETTA,
Appellant

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION
AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION
("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA; and
CITY OF PHILADELPHIA;
THE GENERAL ELECTRIC COMPANY; AND
THE BUDD COMPANY; AND
WESTINGHOUSE ELECTRIC CORPORATION

v.

PENN CENTRAL CORPORATION

(D.C. Civ. No. 86-07417)

No. 92-2005

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MARY RETTA JOHNSON,
Appellant

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA; and
THE CITY OF PHILADELPHIA; and
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY; and
WESTINGHOUSE ELECTRIC CORPORATION; and
PENN CENTRAL CORP.

(D.C. Civ. No. 86-07418)

No. 92-2006

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CELESTE BROWN,
Appellant

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA; and
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION

(D.C. Civ. No. 86-07419)

No. 92-2007

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CLEMMON L. BROWN

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA; AND
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY; AND
WESTINGHOUSE ELECTRIC CORPORATION; AND
PENN CENTRAL CORPORATION
Clemmon Brown, Appellant

(D.C. Civ. No. 86-07420)

No. 92-2008

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CLOYD H. BROWN

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION
AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION
(" AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION
Cloyd Brown, Appellant

(D.C. Civ. No. 86-07421)

No. 92-2009

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

CURTIS BROWN,

Appellant

v.

MONSANTO COMPANY;
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION (" AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA

v.

GENERAL ELECTRIC COMPANY; and
THE BUDD COMPANY; and
WESTINGHOUSE ELECTRIC COMPANY;
PENN CENTRAL CORP.

(D.C. Civ. No. 86-07422)

No. 92-2010

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

JOHN INGRAM, SR., and
PATRICIA INGRAM, in their own right and as parents and natural guardians of JOHN INGRAM, JR.; and APRIL INGRAM in her own right

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION (" AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL"); and
MONSANTO COMPANY ("MONSANTO"); and
GENERAL ELECTRIC COMPANY ("GE"); and
CITY OF PHILADELPHIA ("PHILADELPHIA")

v.

UNITED STATES OF AMERICA;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION
John Ingram, Sr. (and as representative of decedent Patricia Ingram), John Ingram, Jr., Patricia Ingram and April Ingram Robinson-Ray, Appellants

(D.C. Civ. No. 86-07561)

No. 92-2011

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MARY ALICE KNIGHT,
Appellant

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL"); and
MONSANTO COMPANY ("MONSANTO"); and
GENERAL ELECTRIC COMPANY ("GE"); and
CITY OF PHILADELPHIA ("PHILADELPHIA")

v.

UNITED STATES OF AMERICA;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION

(D.C. Civ. No. 87-00712)

No. 92-2014

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

WILLIAM BUTLER; THERESA BUTLER;
MARVIN L. SIMPSON; ALLEN K. SIMPSON;
KAREN R. SIMPSON; DONALD E. SIMPSON; and
BRYAN M. JACKSON

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION
AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION
("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
MONSANTO COMPANY;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION
William Butler, Theresa Butler,
Bryan Jackson, Allen Simpson,
Donald Simpson, Karen Simpson,
and Marvin Simpson, Appellants

(D.C. Civ. No. 87-02874)

No. 92-2016

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MATTHEW CUNNINGHAM; and
BESSIE CUNNINGHAM,
Appellants

v.

MONSANTO COMPANY; and
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION,
Third-Party Defendants

(D.C. Civ. No. 87-05269)

On Appeal From the United States District Court
For the Eastern District of Pennsylvania

Argued: October 26, 1993

Before: BECKER, ROTH, and LEWIS, *Circuit Judges.*

(Filed August 31, 1994)

[As Amended October 17, 1994]

OPINION OF THE COURT

BECKER, *Circuit Judge.*

I. INTRODUCTION

The plaintiffs in this toxic tort case have lived for many years in the vicinity of the Paoli Railyard, a railcar maintetenance facility at which polychlorinated biphenyls (PCBs) were used in profusion for over a quarter century. They have sued to recover damages for a variety of physical ailments and for property damage against the corporations that have maintained the railyard and that sold the PCBs.

This appeal is from the district court's second grant of summary judgment for the defendants. In *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990) ("*Paoli I*"), *cert. denied*, 499 U.S. 961, 111 S. Ct. 1584 (1991), we reversed the grant of summary judgment for defendants and remanded for further proceedings. We did so because the foundation of the summary judgment—the exclusion of virtually all the plaintiffs' expert opinion pursuant to Federal Rules of Evidence 702, 703 and 403—was undermined by (1) the failure of the district court to permit sufficient development of the record upon which a determination to exclude expert evidence might be based, and (2) the district court's failure to make findings, grounded on Fed. R. Evid. 702 or 703, setting forth the basis of its decision.

On remand the district court conducted five days of *in limine* hearings, receiving extensive evidence about the scientific reliability of plaintiffs' expert opinions. It then filed extensive opinions (totalling 330 pages) setting forth not only findings of fact but also its reasons for again excluding the vast bulk of plaintiffs' expert evidence. This appeal followed.

Resolution of the appeal requires that we address myriad issues of procedure, evidence, and substantive law. Primarily, however, we must consider the voluminous record concerning expert opinion and, applying Fed. R. Evid. 702 and the standards enunciated by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), decide whether the district court erred in again excluding the opinions of plaintiffs' experts in connection with its summary judgment determination. *Daubert* requires the district court to act as "gatekeeper" and to assure that the scientific methodology upon which the expert opinion is founded is reliable, i.e., that the expert's conclusion is based on good grounds (the methods and principles of science). We also must deal with Fed. R. Evid. 703 because the district court's exclusion of expert testimony rests, in part, on its conclusion that some of the hearsay evidence upon which the experts relied is not of a kind usually relied on by experts in the field. In this regard we conclude that the precept announced in *In Re: Japanese Electronics Products Antitrust Litigation*, 723 F.2d 238 (3d Cir. 1983), *rev'd on other grounds sub nom., Matsushita Electrical Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 106 S. Ct. 1348 (1986), that the principal arbiters of the reasonableness of reliance upon inadmissible evidence are the experts and not the trial judge, does not survive *Daubert*.

Preliminary to an application of Rules 702-703 to the evidentiary rulings at issue, we must address the question of the proper scope of review. Although review of the district court's fact findings that undergird its rulings on the admissibility of expert opinion is deferential, given the enormous power of the district court to foreclose submission of a party's case to a jury on the basis of a threshold determination of nonreliability of opinion evidence, we conclude that the review requires a "hard look" to insure that the district court's exercise of discretion was sound and that it correctly applied the several *Daubert* factors. Then to the extent that any of the expert opinion survives,

we must determine whether the plaintiffs can avoid summary judgment on any of the claims to which the surviving opinion pertains.

For the most part we affirm the rulings and the judgment of the district court. However, we also reverse in part, and remand some claims for trial. In summary we rule as follows.

1. We affirm the district court's decision to retain jurisdiction in this case based on pendent jurisdiction stemming from the plaintiffs' prior CERCLA claims.

2. We affirm the district court's discretionary ruling allowing certain of defendants' experts to testify at the *in limine* hearings without being deposed; however, we point out that depositions should generally be afforded in future cases of this nature. We do not reach the propriety of its decision excluding plaintiffs' experts for whom no Rule 26(b)(4) statements were filed because plaintiffs do not rely on these experts in opposition to summary judgment.

3. We reverse the district court's exclusion of the opinion of Dr. Janette D. Sherman insofar as it was grounded on the conclusion that she was an unqualified expert. However, we affirm the district court's holding that she could not rely on immunological tests from an unaccredited laboratory. We also affirm the district court's exclusion of the opinions of Dr. Sherman as to causation of plaintiffs' present injuries with respect to those plaintiffs whom she did not examine and whose medical history she did not take. We believe that, in the absence of employment of the standard techniques of differential diagnosis, and in the absence of any good explanation justifying her conclusion in the light of possible alternative causes of plaintiffs' injuries, Dr. Sherman's methodology as to those plaintiffs was not reliable, as the district court found.

4. We affirm the district court's exclusion of the opinion of Dr. G. John DiGregorio with respect to causation of the injuries of those plaintiffs for whom he testified.

Because Dr. DiGregorio neither examined these plaintiffs nor took their medical histories, he did not have a reliable basis from which to conclude they were ill. Moreover, as with Dr. Sherman, in the absence of employment of standard techniques of different diagnosis, and failure to provide any explanation as to why he concluded that PCBs rather than alternative possibilities had caused plaintiffs' illnesses, we conclude that Dr. DiGregorio's assessment of causation was unreliable.

5. We reverse the district court's exclusion from evidence of the opinions of Dr. Sherman with respect to most of the injuries of Bessie Cunningham and Amber Burrell, whom she actually examined and whose medical histories she took. In light of: (1) Dr. Sherman's employment of the standard techniques of differential diagnosis with respect to those plaintiffs, and (2) defendants' failure to point to possible alternative causes of their injuries which Dr. Sherman failed to consider, we are satisfied that, with respect to them, Dr. Sherman's scientific methodology was reliable and that the district court's exclusion of her opinion represented an impermissible jury-like determination that it preferred the defendants' experts' opinion to that of Dr. Sherman.

6. We affirm the district court's exclusion from evidence of the opinion of Dr. Ian Nisbet regarding plaintiffs' exposure to PCBs: (1) insofar as that opinion is based on a recalculation of American Medical Laboratory test ("AML") results to account for the degree to which the laboratory ostensibly underestimated its results; and (2) insofar as it is grounded on "back calculations" of plaintiffs' PCB blood levels in 1986 based upon the results of studies made by the Eco Logic laboratory in 1992. We conclude that Dr. Nisbet's methodology in recalculating the AML tests was unreliable, and that the Eco Logic data from which he began his back calculations was not a type reasonably relied on by experts in the field due to the quality control problems in Eco Logis's methodology.

7. We reverse the district court's exclusion of the remainder of Dr. Nisbet's opinion, including his conclusion that plaintiffs had PCBs in their blood at levels above the background PCB levels in the general population. We are satisfied that Dr. Nisbet's calculation of background blood levels from National Human Adipose Tissue Survey ("NHATS") fat data was based on a reliable methodology, and that the NHATS data was a type of data reasonably relied on by experts.

8. We reverse the district court's exclusion of animal studies. Where, as here, these studies were supported by some epidemiological data and had been used by EPA to conclude that PCBs were a probable human carcinogen, plaintiffs' experts had good grounds for determining that they "fit" a conclusion regarding human causation.

9. We affirm the district court's exclusion of data on chemicals other than PCBs and its exclusion of testimony related to the incidents at Yusho (in Japan) and Yu Cheng (in Taiwan). The district court's conclusion under Fed. R. Evid. 403 that the probative value of this evidence would have been substantially outweighed by unfair prejudice (and would have resulted in significant waste of trial time for resolution of collateral issues) was based on a more than adequate record (one justifying the rare making of the pretrial ruling based on Rule 403), and on findings of fact which, under the applicable standard of review we cannot disturb.

10. We reverse the grant of summary judgment with respect to those personal injury plaintiffs for whom Dr. Sherman's testimony is admissible, concluding that they have demonstrated the existence of a genuine issue of material fact as to whether defendants exposed them to PCBs which caused their present injuries.

11. We reverse the grant of summary judgment with respect to the medical monitoring claims. Although recent changes in Pennsylvania law have interred plaintiffs' increased risk claims, we still believe that the Pennsylvania

Supreme Court would recognize the plaintiffs' medical monitoring claims, and are satisfied that Dr. Sherman's testimony as to the plaintiffs' future risk is sufficient to get them over the summary judgment threshold.

12. We reverse the grant of summary judgment on plaintiffs' claim with respect to diminution in property value. Based on an extrapolation from existing Pennsylvania case law, we predict that where (1) the defendants have caused some physical harm to plaintiffs' property; (2) repair of this damage will not restore the value of the property to its prior level; and (3) there is at least some ongoing risk to the plaintiffs' land, Pennsylvania would allow plaintiffs to recover damages for the diminution of their property value. On the present record, there remains a genuine issue of material fact on the permanency of damage issue.

13. With respect to all other claims, which represent the bulk of plaintiffs' case, the exclusion of expert opinion leaves the plaintiffs with inadequate evidence to survive summary judgment. We will therefore affirm the grant of summary judgment on these remaining claims.

II. FACTS AND PROCEDURAL HISTORY

Beginning in the 1950s, if not before, PCBs were used at the Paoli Railroad Yard (the "Yard") as a fire-resistant insulating fluid in railroad car transformers. PCBs gradually accumulated in the Yard and leaked off the Yard into groundwater and ultimately into the soil of nearby residences. (A1122-1123). Several studies from 1979-1986 documented high levels of PCBs in the Yard and in nearby water and land. The National Institute for Occupational Safety and Health (NIOSH) identifies the site as containing the worst PCB contamination it has ever encountered during a health inspection.

In 1986, the United States sued SEPTA, Conrail and Amtrak under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), 42 U.S.C.

§ 9601, to compel the cleanup of the Yard. After the entry of five consent decrees, which primarily required the control of leakage from the Yard, EPA adopted a final plan, the Record of Decision, in July of 1992. This plan requires extensive excavation and treatment of soils both at the Yard and on nearly residential property and streams, and erosion controls at the Yard.

The palintiffs in this action consist of individuals who lived near the Yard in areas identified by EPA and by the railroad defendants' contractor, Groundwater Technologies, Inc., as having experienced the most severe run-off from the Yard. The plaintiffs have adduced evidence of significant levels of PCBs in the soil at their homes. Many of the plaintiffs played in the soil at their homes while growing up, gardened in it, and ate vegetables grown from it. Many also regularly traversed the Yard on foot as a short cut to their destinations.

In 1986, thirty eight plaintiffs brought suit in the District Court for the Eastern District of Pennsylvania. Some sought recovery for present injuries, (allegedly caused by exposure to PCBs and other assorted chemicals from the Yard, including polychlorinated dibenzo furans ("furans") and polychlorinated dibenzo-p-dioxins ("dioxins")). Some plaintiffs, many of whom have not yet suffered any physical injury, brought claims for emotional distress caused by fear of future injury, and for medical monitoring to decrease the likelihood of the future development of serious diseases. Finally, some of the plaintiffs have brought claims for the decrease in value to their property caused by the presence of PCBs on the land.

The defendants (in some or all of the cases) are Monsanto Corporation, the nation's leading manufacturer of PCBs; General Electric Company, manufacturer of some of the railroad car transformers in which the PCBs were used; Amtrak, owner of the Yard since 1976; Conrail, which operated the facility between 1976 and 1983; the Southeastern Pennsylvania Transit Authority

(SEPTA), which has operated the facility since 1983; and the City of Philadelphia, which is linked with SEPTA. SEPTA filed third-party complaints against Westinghouse Electric Corporation, manufacturer of some of the transformers used at the Yard, and the Budd Company manufacturer of some of the railroad cars. Conrail filed a third part complaint against the Penn Central Corporation.

In November of 1988 the district court granted defendants' motion for summary judgment against all plaintiffs on the personal injury claims because it held that all of plaintiffs' evidence pertaining to significant exposure and causation, necessary elements of their claims, was inadmissible. The court excluded the evidence under Federal Rule of Evidence 702, which requires expert witnesses to be qualified and to use reliable scientific techniques, Rule 703 which requires experts to rely on data of a type reasonably relied upon by experts in the field, and Rule 403 which requires the probative value of evidence not to be substantially outweighed by unfair prejudice or undue delay. *See In re Paoli Railroad Yard PCB Litigation*, 706 F.Supp. 358 (E.D. Pa. 1988).

In *Paoli I*, 916 F.2d at 854, this Court reversed the Rule 703 holdings because the district court had not created a sufficiently detailed factual record on which to base them and had not given "the plaintiffs sufficient opportunity to explore the issues upon which they were ultimately denied relief." We reversed the district court's Rule 702 holdings because it had construed the qualification requirement of Rule 702 too strictly, *see id.* 855-56, and because it had not created a detailed enough factual record to justify exclusion of the experts' opinion under the reliability prong of Rule 702. *See id.* at 858-59. Finally, we reversed the district court's Rule 403 determinations, holding that Rule 403 exclusions should not be granted pre-trial absent a record which is "a virtual surrogate for a trial record." *Id.* at 859-60. We strongly suggested that the district court should have held an *in*

limine hearing before excluding plaintiffs' expert opinion. *Id.* at 859.

Following remand, the district court issued a case management order in June 1991, giving plaintiffs until March 2, 1992 to complete their discovery, and until March 17, 1992 to designate their trial experts and provide defendants with their experts' reports. The court required the defendants to do likewise one month after plaintiffs.

The list of expert witnesses designated by the plaintiffs in March of 1992 was considerably different from the list at the time of the 1988 summary judgment. The twenty-three plaintiffs represented by the Kohn, Nast, & Graf, and Klehr, Harrison, Harvey, Branzburg, Ellers, & Weir law firms (the "Kohn/Klehr" plaintiffs) named three experts supporting their personal injury claims: Melvyn Kopstein, Ph.D., to testify about the Paoli residents' opportunities for exposure to PCBs from the Yard; Ian C.T. Nisbet, Ph.D., to testify about the plaintiffs' exposure to PCBs; and Janette Sherman, M.D., to testify that PCBs had caused plaintiffs' injuries and that plaintiffs require medical monitoring to detect and treat future PCB-related illnesses.

Defendants moved *in limine* to exclude the opinions of each of these experts under Fed. R. Evid. 702, 703 and 403. On the same grounds, defendants filed motions *in limine* to preclude the plaintiffs' experts from testifying about animal studies purporting to show the harmful effects tof PCBs, evidence concerning the harm of dioxins and furans (chemicals that are sometimes present in transformer fluids), and evidence concerning the "Yusho" incident in Japan and the "Yu Cheng" incident in Taiwan in which many individuals suffered adverse effects after consuming rice oil contaminated with PCBs and furans.

Bruce Hanes, who represented the nine remaining plaintiffs (the "Hanes plaintiffs"), designated Dr. G. John DiGregorio, M.D. to testify that PCBs had caused their

injuries, and Arnold Schechter, M.D., M.P.H., to testify that their fear of future illness was reasonable. In joint pretrial memorandum filed on July 17, 1992, the Kohn/Klehr and Hanes plaintiffs designated three additional trial experts— Deborah Barsotti, Ph.D., Benjamin Calesnick, M.D., and Arthur Zahalsky, Ph.D.—who had offered opinions for the plaintiffs in 1988. They also listed William J. Nicholson, Ph.D. and Cate Jenkins, Ph.D. as fact witnesses. Defendants moved to exclude these witnesses because plaintiffs had failed to designate them as experts in March, as the district court's pre-trial order had required.

The district court held five days of *in limine* hearings between July 28 and August 7, 1992. Drs. Kopstein, Nisbet, and Sherman testified for the plaintiffs. Ten physicians and scientists testified for the defense. On October 21, 1992, the court entered orders excluding all but one of plaintiffs' experts (Dr. Kopstein). The court also excluded evidence concerning animal studies, dioxins and furans, and the incidents at Yusho and Yu Cheng. The court then granted summary judgment against the plaintiffs on their personal injury claims.

The court explained that under our holding in *Paoli I*, the plaintiffs had to establish the following elements to make out a prima facie case: (1) that the defendants had released PCBs into the environment; (2) that the plaintiffs had somehow ingested those PCBs into their bodies; (3) that the plaintiffs have an injury; and (4) that PCBs are the cause of their injury. *See Paoli I*, 916 F.2d at 860. Not surprisingly, after excluding plaintiffs' experts, the court found that plaintiffs had no evidence on either exposure or causation and thus could not prove elements 2, 3, and 4. For similar reasons, the court granted summary judgment against the plaintiffs on their medical monitoring claims.

Nine plaintiffs—Mabel Brown, K. Louise Jones, James Lament, Christopher Brown, Margherita Barbetta, Mary Retta Johnson, John Ingram, William Butler, and Matthew Cunningham—also brought property damage claims against the defendants. The district court granted summary judgment in favor of the defendants on these claims as well. The court held that Pennsylvania law only allows recovery for diminution of a property's market value if there has been permanent damage to the property; and the court found that plaintiffs could not prove such permanent damage in light of EPA's proposed cleanup plan.

The plaintiffs challenge the district court's subject matter jurisdiction, all of its admissibility decisions, its legal conclusions regarding diminution of a property's market value, and the court's grant of summary judgment. We will affirm most of the district court's decisions. We reverse only its grant of summary judgment on a number of the present injury claims of Bessie Cunningham and Amber Burrell, and its grant of summary judgment on the plaintiffs' claims for medical monitoring and diminution in property value.

III. SUBJECT MATTER JURISDICTION OF THE DISTRICT COURT [1]

Plaintiffs' original claims in 1986 included a CERCLA claim, 42 U.S.C. § 9600 *et seq.*, which conferred federal question jurisdiction, 28 U.S.C. § 1331(a), on the district court. The court possessed pendent jurisdiction over plaintiffs' other claims. However, plaintiffs voluntarily dismissed the CERCLA claim after our ruling in *Paoli I*. Plaintiffs contend that, after this dismissal, the district court no longer had subject matter jurisdiction over the case because, absent the CERCLA claim, there was no

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[1] Appellate jurisdiction is predicated on 28 U.S.C. § 1291.

federal question jurisdiction; nor was there complete diversity.[2]

In *United Mine Workers v. Gibbs*, 383 U.S. 715, 86 S. Ct. 1130 (1966), the Supreme Court held that in evaluating whether to exercise pendent jurisdiction, a district court must weigh "considerations of judicial economy, convenience and fairness to [the] litigants," 383 U.S. at 726, 86 S. Ct. at 1139.[3] In holding that these factors favored retention of jurisdiction here, the district court acted within the ambit of its discretion.

Considerations of judicial economy clearly weighed in favor of the district court retaining jurisdiction. Although considerations of judicial economy alone are generally insufficient to justify a district court's decision to retain

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[2] In 1990 Congress enacted 28 U.S.C. § 1367 which codifies principles governing pendent jurisdiction for civil actions commenced after December 1, 1990. However, that statute does not apply to this case, which was filed in 1986.

[3] Plaintiffs rightly note that, except under extraordinary circumstances, these considerations militate against a district court retaining pendent jurisdiction when there are no longer any federal claims. *See Shaffer v. Board of Sch. Directors*, 730 F.2d 910, 913 (3d Cir. 1984). Nonetheless, this is a discretionary decision for the district court. Although in *Gibbs*, the Supreme Court stated that, "[n]eedless decisions of state law should be avoided . . . Certainly, if the federal claims are dismissed before trial, even though not insubstantial in a jurisdictional sense, the state claims should be dismissed as well," 383 U.S. at 726, 86 S. Ct. at 1139, we have explained that:

> [t]his sentence appeared . . . in the context of a discussion of [the] discretionary nature of pendent jurisdiction. Moreover, in *Rosado* [*v. Wyman*], 397 U.S. 397[, 403], 90 S. Ct. 1207[, 1213-14] (1969), the Court upheld an exercise of pendent jurisdiction despite the pretrial dismissal of the underlying claim and in so doing confirmed that an early dismissal of a federal claim would not deprive a court of constitutional power to hear a pendent claim.

Lentino v. Fringe Employee Plans, Inc., 611 F.2d 474, 479 n. 4 (3d Cir. 1979).

jurisdiction, *see Shaffer v. Board of Sch. Directors,* 730 F.2d 910, 912 (3d Cir. 1984); *Lovell Mfg. v. Export-Import Bank of U.S.,* 843 F.2d 725, 734-35 (3d Cir. 1988), we have held such concerns sufficient when they are especially strong. In *Lentino v. Fringe Employee Plans, Inc.,* 611 F.2d 474, 480 (3d Cir. 1979), we upheld a district court's decision to retain jurisdiction over a state law claim when plaintiffs dropped their federal claims on the morning of trial after there had already been a year of pretrial proceedings.

The concerns of judicial economy here are at least as strong as they were in *Lentino.* Although the plaintiffs dropped their CERCLA claim much earlier than the morning before trial, far more energy had been invested in the proceedings here than in *Lentino.* Six years of federal proceedings had occurred before the plaintiffs dropped their CERCLA claim, including extensive discovery. Moreover, the concern over judicial economy was combined here with two other factors strongly militating in favor of retention of jurisdiction.

First, the district court would have continued to have jurisdiction over plaintiffs' claims against Amtrak, *see* 28 U.S.C. § 1349 (providing district court jurisdiction over all corporations incorporated by an act of Congress in which the United States owns more than half the stock) even if it had dismissed most of plaintiffs' claims for lack of jurisdiction. Amtrak doubtless would then have impleaded the other defendants, all of whom had deep pockets, thus changing the alignment of the parties but not the nature of the litigation. In such circumstances, a district court acts within its discretion in retaining jurisdiction. *Cf. New Jersey Dept. of Envtl. Prot. v. Gloucester Envtl. Mgmt. Services, Inc.,* 719 F.Supp. 325, 337 (D.N.J. 1989), retaining jurisdiction in order to prevent "a litigation merry-go-round").

Second, plaintiffs were the ones who initially filed their claims in federal court and obtained a 1986 ruling that

the CERCLA claims created federal jurisdiction. Plaintiffs dismissed their CERCLA claims and argued against federal jurisdiction only after the district court had first granted summary judgment against them. Thus, plaintiffs' dismissal of their CERCLA claims may well constitute an attempt to forum shop by divesting the district court of jurisdiction. In *Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 108 S. Ct. 614 (1988), the Supreme Court held that the possibility of forum shopping is one factor a district court should take into account in exercising its discretion with respect to pendent jurisdiction. *See id.* at 351, 356, 357 & n.12, 108 S. Ct. at 619, 622-23 & n.12.

Cohill, to be sure, was not about whether a district court should retain jurisdiction, but rather about what a district court should do after deciding not to retain jurisdiction, i.e. whether the court should dismiss the case, which might end it due to statute of limitations problems in state courts, or whether the court should remand the case to the state court from whence it had been removed. But *Cohill* did hold that one factor the district court should consider in deciding whether to remand the case to state courts is whether plaintiffs are attempting to forum shop. We hold that the same principle applies when the district court decides whether to retain jurisdiction in the first place.

In sum, fairness to defendants along with judicial economy and convenience justify the district court's decision to retain jurisdiction here.

IV. WAS THE *IN LIMINE* HEARING TAINTED BY UNFAIR PROCEDURES?

Before addressing the central issues in the case (regarding the admissibility of the opinions of the plaintiffs' experts under Rules 702, 703 and 403), we must dispose of some preliminary questions. The plaintiffs contend that the district court should not have relied on the testimony of the defendants' experts in excluding the tes-

timony of the plaintiffs' experts, because the defendants failed to designate these experts in accord with the time schedule announced by the district court. We review for abuse of discretion, and find none with respect to this ruling.

Plaintiffs also submit that the district court should not have relied on its scheduling order to exclude the testimony of some of plaintiffs' proposed experts. We do not have to reach the merits of this contention, because plaintiffs did not point to the testimony of these experts in opposition to summary judgment.

A. *Inadequate Opportunity to Depose Defense Experts*

On June 4, 1991, the district court issued an order requiring defendants to "designate all *trial* expert witnesses" by April 17, 1992 and giving the parties "until June 17, 1992 to depose expert witnesses." (emphasis added). On June 25, 1992, well after the deadline the district court had set for identification of experts, defendants submitted affidavits from a new set of experts. Defendants intended to have these experts testify at the August *in limine* hearing but not at trial. Because discovery was closed, plaintiffs were unable to depose them.

Plaintiffs moved to prevent these experts from testifying. The district court never ruled on this motion, allowed the experts to testify at the *in limine* hearing, and relied on their testimony in excluding much of plaintiffs' evidence. Plaintiffs contend that this was error. On a purely formal level, we disagree for, as defendants correctly assert, the district court's June 1991 order setting deadlines for the identification of experts was only directed at *trial* witnesses and said nothing about witnesses who were to testify only at the *in limine* hearing. But that conclusion does not settle the question. By coincidence, plaintiffs' more significant claim of error is encapsulated in a recent law review article by Professor Berger,

who argues that "[c]ourts should not permit the defendant to obtain a hearing on a motion in limine by relying on affidavits from experts unless their identity and reports have been supplied to the plaintiff in the course of discovery and the plaintiff had an opportunity to depose [them]" Margaret A. Berger, *Procedural Paradigms for Applying the* Daubert *Test*, 78 Minn. L. Rev. 1345, 1372 (1994).

The district court certainly had the power to provide that the experts who were to testify at the *in limine* hearing be subject to discovery. *See* Berger, *supra*, at 1372 n.141. ("A court undoubtedly has power pursuant to Federal Rule of Civil Procedure 16 to require parties to provide each other with expert reports and an opportunity for the deposition of experts retained in connection with in limine motions."). And we generally agree with Professor Berger that because under *Daubert* a judge at an *in limine* hearing must make findings of fact on the reliability of complicated scientific methodologies and this fact-finding can decide the case, it is important that each side have an opportunity to depose the other side's experts in order to develop strong critiques and defenses of their expert's methodologies. *See Paoli I*, 916 F.2d at 854 ("[T]he detailed factual record requirement, firmly entrenched in our jurisprudence, requires adequate process at the evidentiary stage, particularly when a summary judgment may flow from it." (internal citations omitted)). Given the "liberal thrust" of the federal rules, *see Daubert*, 113 S. Ct. at 2794 (internal quotation omitted), it is particularly important that the side trying to defend the admissibility of evidence be given an adequate chance to do so. Moreover, fairness suggests that each side should have an equal opportunity to depose the other side's experts.[4]

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[4] Rule 104(a) generally allows a trial court conducting a pre-trial hearing to consider evidence that would not be admissible at trial. As we stated in *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), during a pre-trial admissibility hearing, a "trial court may

In this case, however, where we had yet to articulate our specific concern with depositions prior to the ruling of the district court, we conclude that the district court did not abuse its discretion in allowing experts, who had provided affidavits, to testify at the *in limine* hearing without being deposed.[5] Moreover, the defendants submitted the affidavits of their experts four weeks prior to the hearing, so that the plaintiffs had a significant opportunity to prepare for the testimony of defendants' experts. They also had extensive leeway *at* the *in limine* hearing, where the conservation of the time of the jury was not implicated, to consult with their experts regarding any new arguments presented by defendants experts. Under these circumstances, whatever unfairness to the plaintiffs that resulted from their inability to depose defendants' experts is not sufficient to warrant a reversal for depositions and a new *in limine* hearing.

B. *Exclusion of Opinion of Experts for Whom No. 26 (b)(4) Statements Were Filed*

In the June 4, 1991, scheduling order setting deadlines for designation of defense experts discussed above, the district court required plaintiffs to designate on or before March 17, 1992, "all trial expert witnesses and provide defendants with the substance of their trial testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4)." On July 17, 1992, four months after the deadline for designating experts and two weeks before the scheduled trial date, the plain-

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consider, *inter alia*, offers of proof, affidavits, stipulations . . ." 753 F.2d at 1241. By announcing a general presumption in favor of depositions before *Daubert* hearings, we do not intend to imply that all procedural protections of a trial apply at an *in limine* hearing. But depositions should generally be allowed in connection with a *Daubert* exercise.

[5] We note that plaintiffs themselves relied on the expert testimony of Richard Glerzcak, who had not been designated as a trial expert.

tiffs filed a joint pretrial memorandum in which they named three expert witnesses, Drs. Calesnick, Barsotti, and Zahalsky, who had not been identified in plaintiffs' March 1992 Rule 26(b)(4) statements. Plaintiffs also named Drs. Nicholson and Jenkins as fact witnesses even though defendants argue that they have no connection with this case and are really expert witnesses. The district court excluded all of these witnesses on the basis that plaintiffs had not named them by March 17, 1992.

Plaintiffs assert that because Drs. Calesnick, Barsotti, and Zahalsky provided opinions in 1988 before the *first* summary judgment decision, the plaintiffs had designated them as experts *before* March 17, 1992, as required by the district court's scheduling order. Moreover, plaintiffs argue, even if they violated the pre-trial order, the district court abused its discretion in sanctioning them by excluding the witnesses under the factors we set forth in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977). We do not reach the merits of the district court's ruling.

Plaintiffs did not rely on these witnesses to oppose summary judgment. In fact, the plaintiffs did not even list these witnesses as trial witnesses until July 17, nine days after they had filed their opposition to summary judgment. As a result, our consideration of whether the district court was correct to grant summary judgment does not depend on whether the district court properly excluded these witnesses. "Where a party opposing a motion for summary judgment has the burden of persuasion, and the moving party has identified sufficient facts of record to demonstrate that no genuine issue of material fact remains, the nonmoving party is obliged to identify those facts of record which would contradict the facts identified by the movant." *Childers v. Joseph*, 842 F.2d 689 (3d Cir. 1988). *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552-53 (1986). If the plaintiffs wished to rely on the opinions of Drs. Calesnick

Barsotti, Zahalsky, Nicholson and Jenkins to oppose summary judgment, they were required to identify the relevant facets of this testimony in their opposition to summary judgment.

Nonetheless, because we are reversing the grant of summary judgment with respect to some plaintiffs and some issues, whether these witnesses can testify at trial may still matter on remand. We could therefore decide whether the district court's original decision excluding these witnesses was an abuse of discretion, the matter having been properly put before us. However, we decline to do so, preferring to allow the district court to reconsider its decision in light of the additional time that will be available to the defendants to depose the witnesses.

In excluding the witnesses originally, the district court partly relied on the proximity of the trial date to the revelation by plaintiffs of their intent to call these experts. And proximity is indeed one important factor.[6]

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[6] *Compare Semper v. Santos*, 845 F.2d 1233, 1237-38 (3d Cir. 1988) (upholding the district court's exclusion of an expert witness who had not been named by the deadline set by the court, where the existence of the expert only became apparent *one day before trial* and where the expert's testimony was not that important); *Coleco Industries Inc. v. Berman*, 567 F.2d 569-70 & n.14 (3d Cir. 1977) (upholding the district court's exclusion of a study propounded by plaintiff's expert *in the midst of a complex trial* where counsel had no excuse for its failure to advise the court of the testimony in accord with the court's prior order); *United States v. 68.94 Acres of Land*, 918 F.2d 389, 396-97 (3d Cir. 1990) (upholding the exclusion of plaintiff's expert when, *at trial*, the expert relied on data that plaintiffs had failed to disclose in accord with a pretrial order); *with Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d (3d Cir. 1977) (reversing the exclusion of the witnesses' testimony where the failure to include the witnesses in the pretrial memoranda was not a result of bad faith but of late discovery of the witnesses, the plaintiff informed the defendant of the discovery of the witnesses *three weeks before trial* but defendant did not attempt to gain information about these witnesses; and the possibility existed of postponing the trial for a few days, conducting further discovery and taxing the costs to the plaintiff).

When the plaintiffs named these experts in July of 1992, two weeks before trial, giving defendants a significant time to depose them would have required delaying a long scheduled trial in a complex case that had already gone on for years. But after remand, the district court will easily be able to give the defendants significant time to depose the plaintiffs. In sum, in light of the changed circumstances that will be present upon remand, we choose not to determine whether the district court's original decision constituted an abuse of discretion.

V. LEGAL STANDARDS FOR THE ADMISSIBILITY OF EXPERT OPINION

The district court excluded plaintiffs' remaining experts under Rules 702, 703, and 403. While the district court, the plaintiffs, and the defendants basically agree on the legal standards to be applied in analyzing admissibility, they also have some significant differences which repeatedly surfaced throughout the disputes over the admissibility of particular testimony. Accordingly, before analyzing the admissibility of the testimony of particular experts, we will first provide an overview of the legal standards under which we will evaluate that admissibility. Such an overview is also important in light of the Supreme Court's recent decision in *Daubert,* which, although it largely adopted the Rule 702 test we announced in *Downing,* works certain changes in our jurisprudence on the admissibility of expert opinions.

A. *Rule 702*

Rule 702 provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

1. Qualifications

Rule 702 has two major requirements. The first is that a witness proffered to testify to specialized knowledge must be an expert. We have interpreted this requirement liberally. *See Paoli I*, 916 F.2d at 855. We have held that a broad range of knowledge, skills, and training qualify an expert as such. *See id.* at 855. In *Paoli I* we ruled that the district court had abused its discretion in excluding the opinions of Drs. Barsotti, Zahalsky, and Nisbet. We explained that exclusion was not the proper remedy "simply because the experts did not have the degree or training which the district court apparently thought would be most appropriate." *Id.* at 856.

Defendants submit that when this court held that Rule 702 mandates a policy of liberal admissibility, all that it was doing was eliminating any requirement that a candidate have specific formal qualifications such as a degree in a particular field. They assert that we were simply directing the trial court to focus on the "substance of a proffered expert's background and its fit with respect to the issue at hand." Thus, defendants suggest, when a trial court evaluates an expert's substantive rather than formal qualifications, it does not have to use a liberal policy of admission.

But this is incorrect. Rule 702's liberal policy of admissibility extends to the substantive, as well as the formal qualification of experts. We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications. *See Hammond v. International Harvester Co.*, 691 F.2d 646, 652-53 (3d Cir. 1982) (holding that an engineer, whose only qualifications were sales experience in the field of automotive and agricultural equipment and teaching high school automobile repair, nevertheless could testify in a products liability action involving tractors); *Knight v. Otis Elevator Co.*, 596 F.2d 84, 87-88 (3d Cir. 1979) (holding that an expert could testify that unguarded ele-

vator buttons constituted a design defect despite expert's lack of specific background in design and manufacture of elevators). As we explain below, however, the level of expertise may affect the reliability of the expert's opinion.

2. Reliability

The second requirement of Rule 702 is that the expert must testify to "scientific, technical or other specialized knowledge [that] will assist the trier of fact." Fed. R. Evid. 702. The Supreme Court recently evaluated the meaning of this requirement in *Daubert* and held that Rule 702 does not incorporate the common law *Frye* rule in which expert testimony is admissible only insofar as it is based on a technique generally accepted in the scientific community. Instead, the Supreme Court agreed with this Court's basic holding in *Downing* that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable. *See Daubert*, 113 S. Ct. at 2794-95 ("That the *Frye* test was displaced by the Rules of Evidence does not mean, however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence. Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."); *Downing* 753 F.2d at 1237. *Daubert* explains that the language of Rule 702 requiring the expert to testify to *scientific knowledge* means that the expert's opinion must be based on the "methods and procedures of science" rather than on "subjective belief or unsupported speculation"; the expert must have "good grounds" for his or her belief. *Daubert*, 113 S. Ct. at 2795. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. *Id.* at 2795 n.9.

Daubert suggests several factors that a district court should take into account in evaluating whether a particular scientific methodology is reliable (i.e. scientifically valid), including the testability of the expert's hypothesis ("whether it can be (and has been) tested"), *Daubert*, 113 S. Ct. at 2796, whether the methodology has been subjected to peer review and publication, the frequency by which the methodology leads to erroneous results, the existence and maintenance of standards controlling the technique's operation, and whether the methodology has been generally accepted in the scientific community.[7] *See Daubert*, 113 S. Ct. at 2796-97. We listed very similar factors a district court should consider in *Downing*. *See Downing*, 753 F.2d at 1238-39. *Daubert* lists two factors not listed in *Downing*—whether a method produces testable hypotheses and the existence of standards controlling the technique's operation, and *Daubert* leaves off its list several factors listed in *Downing*—the degree to which the expert testifying is qualified, the relationship of a technique to "more established modes of scientific analysis," and the "non-judicial uses to which the scientific technique are put." *Downing*, 753 F.2d at 1238-39; *see Daubert*, 113 S. Ct. at 2796-97. But *Daubert* specifically refuses to disavow any the particular factors we listed in *Downing*. *See* Daubert, 113 S. Ct. at 2797 n.12. And *Daubert*, like *Downing*, indicates that the inquiry as to whether a particular scientific technique or method is reliable is a flexible one. *See id.* at 2796, *Downing*, 753 F.2d at 1238-39. We now make clear that a district court should take into account all of the factors

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[7] It is important to stress that both *Daubert* and *Downing* hold that although peer review and general acceptance are not necessary conditions of reliability, they are factors a district court can take into account in assessing reliability. *See Downing*, 753 F.2d at 1238, *Daubert*, 113 S. Ct. at 2797.

listed by either *Daubert* or *Downing* as well as any others that are relevant.[8]

3. Fit

In addition to reliability, Rule 702 requires that the expert's testimony must assist the trier of fact. As we put it in *Downing*, admissibility depends in part on "the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *Downing*, 753 F.2d at 1237. *See Daubert*, 113 S. Ct. at 2795-96 (explicitly adopting the "fit" requirement of *Downing*). For example, animal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans. *Daubert* explains that, " '[f]it' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id.* at 2796. Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*. "Rule 702's 'helpfulness' standard requires a valid *scientific* connection to the pertinent inquiry as a precondition to admissibility." *Id.* (emphasis added). For example, in order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapo-

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[8] Thus, the factors *Daubert* and *Downing* have already deemed important include: (1) whether a method consists of a testable hypothesis, (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

late from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or "good grounds," extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case.

4. The roles of judge and jury: how high a threshold for reliability?

Plaintiffs' basic position in their challenge to each of the district court's admissibility decisions is that the district court improperly usurped the role of the jury by the manner in which it analyzed admissibility. Plaintiffs first argue that, so long as they have made a prima facie showing that an expert's testimony is reliable, it is up to the jury to evaluate the expert's testimony. They assert that for the judge to evaluate competing evidence on reliability before determining admissibility would force plaintiffs to prove their case twice—once to the judge in order to persuade him or her to admit the evidence and once to the jury to persuade it of liability.

But plaintiffs' position that a party who wants to introduce expert testimony must make only a prima facie showing that a technique is reliable (*e.g.*, the testimony of a single qualified expert) is specifically foreclosed by precedent. *Daubert* holds that admissibility under Rule 702 is governed by Rule 104(a), which requires the judge to conduct preliminary factfinding, to make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid," and thus enables the judge to exclude evidence presented in plaintiffs' prima facie case.[9] *Daubert*, 113 S. Ct. at 2796. Similarly, we held in *Downing* that "it is plain that the proponent must make more than a *prima facie* showing

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[9] Rule 104(a) states that:

> Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibil-

. . . that a technique is reliable." *Downing*, 753 F.2d at 1240 n.21. We added that, in contrast to the view that the admission of scientific testimony is a matter of conditional relevancy governed by Rule 104(b), "novel scientific evidence carries with it concerns over trustworthiness and reliability akin to those raised by offers of hearsay evidence. When there is a serious quuestion of reliability of evidence, it is appropriate for the court to exercise to some degree an evidentiary screening function." *Id. Cf. In re Japanese Electronic Products*, 723 F.2d 238, 276-77 (3d Cir. 1983) (implying that Rule 104(a) requires judges to make factual evaluations in making Rule 703 determinations).[10]

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ity of evidence shall be determined by the court, subject to the provisions of subdivision (b).

Rule 104(b) concerns evidence that is relevant only if certain facts are true. It directs the judge to admit such evidence provided a party provides prima facie evidence of the truth of those facts. It provides that "[w]hen the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition." Fed. R. Evid. 104(b). By holding that the admissibility of scientific testimony is governed by Rule 104(a), *Daubert* clearly holds that the party seeking admissibility must make out more than a prima facie case of reliability.

[10] Plaintiffs cite *Paoli I*, 926 F.2d at 858, for the proposition that the standard for admissibility, at least with respect to accepted methodologies, is whether a reasonable person could believe the results of the scientific study. But when *Paoli I* spoke of an accepted methodology, it meant a methodology that met all the requirements of Rules 702 and 703. Only after meeting such requirements does the question become whether the methodology produced evidence sufficient to survive summary judgment—in other words whether a reasonable person could believe it.

Although *Downing* could be read to imply that scientific techniques that are not novel are automatically admissible, *see Downing*, 753 F.2d at 1232 (evidence based on techniques of uncontroverted validity is readily admissible; evidence based on novel techniques is subject to the *Downing inquiry*), we made it completely clear in *De Luca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 n. 13 (3d Cir. 1990), that the *Downing* inquiry applies whenever

This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.[11] As the Supreme Court has explained in describing the effect of the preponderance standard of Rule 104(a) generally, "[t]he inquiry made by a court . . . is not whether the proponent of the evidence wins or loses his case on the merits, but whether the evidentiary Rules have been satisfied." *Bourjaily v. United States*, 483 U.S. 171, 175, 107 S. Ct. 2775, 2778 (1987).

The evidentiary requirement of reliability is lower than the merits standard of correctness. *Daubert* states that a judge should find an expert opinion reliable under Rule 702 if it is based on "good grounds," *i.e.*, if it is based on the methods and procedures of science. A judge will often think that an expert has good grounds to hold the

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"helpfulness" cannot be resolved by judicial notice. In other words, scientific testimony must always meet a helpfulness standard; if it is a technique of uncontroverted validity, this inquiry can be resolved by judicial notice. In *Daubert*, the Supreme Court agreed, finding that Rule 702 does not just apply to novel techniques, though noting that some techniques are so well established that judicial notice of their reliability is appropriate. *See Daubert*, 113 S. Ct. at 2796 n. 11.

[11] *Downing* "decline[d] to specify the foundational showing required for admissibility in traditional burden of proof terms, . . . because the balancing analysis incorporates important policy elements . . . which render the determination something more than a fact-finding." 753 F.2d at 1240. However, the Supreme Court subsequently made clear that judges should find facts under Rule 104(a) using a preponderance standard. In *Bourjaily v. United States*, while assessing the burden of proof for the admissibility of a co-conspirator's statement, the Supreme Court held that, "[w]e are therefore guided by our prior decisions regarding admissibility determinations that hinge on preliminary factual questions. We have traditionally required that these matters be established by a preponderance of proof . . ." 483 U.S. 171, 175, 107 S. Ct. 2775, 2778-79 (1987). And *Daubert* specifically applies this holding in the expert opinion context. *See Daubert*, 113 S. Ct. at 2796 n. 10.

opinion that he or she does not even though the judge thinks that the opinion is incorrect. As *Daubert* indicates, "[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 113 S. Ct. at 2797. The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion, and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.

As we explained in *Paoli I*, "the reliability requirement must not be used as a tool by which the court excludes all questionably reliable evidence." *Paoli I*, 916 F.2d at 857. The "ultimate touchstone is helpfulness to the trier of fact, and with regard to reliability, helpfulness turns on whether the expert's "technique or principle [is] sufficiently reliable so that it will aid the jury in reaching accurate results.' " *De Luca*, 911 F.2d at 956 (quoting 3 J. Weinstein & M. Berger, *Weinstein's Evidence* 702[03], at 702-35 (1988)).[12] A judge frequently should find an expert's methodology helpful even when the judge thinks that the expert's technique has flaws sufficient to render the conclusions inaccurate. He or she will often still believe that hearing the expert's testimony and assessing its flaws was an important part of assessing what conclusion was correct and may certainly still believe that a jury attempting to reach an accurate result should consider the evidence.

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[12] An argument could be made that because *Daubert's* reliability requirement is grounded in the scientific knowledge language of Rule 702 rather than the language about assisting the trier of fact which grounded our opinion in *Downing*, the helpfulness inquiry is not what is important. *Daubert's* requirement of "good grounds" potentially requires more than helpfulness. Yet we think that helpfulness is still conceptually important—an expert's testimony is sufficiently grounded for the purposes of litigation only if it will help the trier of fact to reach accurate results.

See Paoli I, 916 F.2d at 857 (helpfulness requires more than bare logical relevance, but there is a strong preference for admission) (citing *Downing*, 753 F.2d at 1235).

The same standard of reliability extends to the step in the expert's analysis that "fits" his or her conclusions to the case at hand. Once again, we emphasize that the standard is not that high. For example, in *Paoli I*, we held that testimony that PCBs cause liver cancer "fit" the case even in the absence of plaintiffs who had liver cancer, because an expert's affidavit suggested that increased risk of liver cancer was probative of increased risk of other forms of cancer. *See Paoli I*, 916 F.2d at 858. Nonetheless, the standard is higher than bare relevance.[13]

In addition to arguing that the district court usurped the role of the jury by requiring more than a prima facie showing of reliability, plaintiffs submit that the district court mistakenly applied the reliability inquiry to expert testimony that should not have been subject to that inquiry. Both *Daubert* and *Downing* require that expert testimony be based on the methods and procedures, the processes and techniques of science. In *Paoli I* we suggested that so long as any deviation the expert made from a reliable method merely constituted a change in the *application* of that method, the expert's testimony remained based on a reliable scientific method. We thought that ferreting out misapplication fell within the province of the jury, and that only if the expert so altered a reliable methodology as to skew it would the reliability inquiry of *Downing* be applicable to the altered methodology. *See*

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[13] *Daubert's* statement that fit "goes primarily to relevance" is not to the contrary. 113 S. Ct. at 2795. This statement elucidates what the fit requirement is about—that the scientific knowledge must be connected to the question at issue—rather than the standard for evaluating that connection. The passages in *Daubert* quoted in the text *supra*, which indicate that the connection between the scientific knowledge and the case must itself constitute scientific knowledge, demonstrate that the standard for fit is higher than bare relevance.

Paoli I, 916 F.2d at 858. Plaintiffs assert that the district court applied the *Downing* inquiry to methodologies that merely constituted slight alterations of reliable methodologies.

However, after *Daubert*, we no longer think that the distinction between a methodology and its application is viable. To begin with, it is extremely elusive to attempt to ascertain which of an expert's steps constitute parts of a "basic" methodology and which constitute changes from that methodology. If a laboratory consistently fails to use certain quality controls so that its results are rendered unreliable, attempting to ascertain whether the lack of quality controls constitutes a failure of methodology or a failure of application of methodology may be an exercise in metaphysics. Moreover, any misappliaction of a methodology that is significant enough to render it unreliable is likely to also be significant enough to skew the methodology.

As suggested, *Daubert* inters any need for us to make such a distinction, for *Daubert*'s requirement that the expert testify to scientific knowledge—conclusions supported by good grounds for each step in the analysis—means that *any* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.*[14]

Finally, plaintiffs contend that the district court usurped the role of the jury by making admissibility decisions based on its disagreement with the *conclusions* of plaintiffs' experts. Plaintiffs are correct, of course, that *Daubert* requires the judge's admissibility decision to focus not on

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[14] Of course, if a court finds that an expert has employed a methodology only slightly different from a methodology that the court thinks is clearly reliable, the court should be more likely to accept the altered methodology than if it was evaluating that methodology as an original matter.

the expert's conclusions but on his or her principles and methodology. *See Daubert,* 113 S. Ct. at 2797. But we think that this distinction has only limited practical import. When a judge disagrees with the conclusions of an expert, it will generally be because he or she thinks that there is a mistake at some step in the investigative or reasoning process of that expert. If the judge thinks that the conclusions of some other expert are correct, it will likely be because the judge thinks that the methodology and reasoning process of the other expert are superior to those of the first expert. This is especially true given that the expert's view that a particular conclusion "fits" a particular case must itself constitute scientific knowledge—a challenge to "fit" is very close to a challenge to the expert's ultimate conclusion about the particular case, and yet it is part of the judge's admissibility calculus under *Daubert.*[15]

Thus, as we explained above, we think that the primary limitation on the judge's admissibility determinations is that the judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks "good grounds" for his or her conclusions.

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[15] The methodology/conclusion distinction remains of some import, however, to the extent that there will be cases in which a party argues that an expert's testimony is unreliable because the conclusions of an expert's study are different from those of other experts. In such cases, there is no basis for holding the expert's testimony inadmissible. *See Hines v. Conrail,* 926 F.2d 262, 274 (3d Cir. 1991) ("though [the expert's] opinion could be considered to be 'novel,' it appears that . . . his methods were not"); Kenneth J. Chesebro, *Taking* Daubert's *"Focus" Seriously: The Methodology/Conclusion Distinction,* 15 Cardozo L.Rev. 1747, 1748 (1994) ("It is completely inappropriate for either the proponent of scientific testimony or her opponent to advance Rule 702 admissibility arguments that depend on the ultimate conclusion reached by an expert.").

5. Confusion—Rule 403

In *Downing* we explained that under Rule 702, admissibility of scientific testimony turns not only on reliability but also on the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury. *See Downing*, 753 F.2d at 1240. We held that in conducting this balancing inquiry, there is a presumption of helpfulness. *See id.* at 1241 (citing *Japanese Electronics*, 723 F.2d at 279). The extent to which an adverse party has had notice and the opportunity to present his or her own experts is also relevant. Moreover, a district court cannot exclude a scientific technique as too confusing and overwhelming simply based on its conclusion that scientific techniques by their very nature confuse and overwhelm the jury. There must be something about the particular scientific technique such as its posture of mythic infallibility that makes it especially overwhelming. *See id.* at 1239 (overturning the district court's exclusion of Dr. Nicholson's meta-analysis because it conclusion that his testimony was overwhelming was based merely on its scientific nature and his credentials).

We explained in *Downing* that Rule 702 analysis partly incorporates Rule 403 analysis but leaves some room for Rule 403 to operate independently. *See Downing*, 753 F.2d at 1242. For example, we noted that a judge might use Rule 403 to exclude an expert's critique of eyewitness testimony even though the critique met the requirements of Rule 702 if there was evidence of defendant's guilt other than eyewitness testimony which would make efforts to criticize eyewitness testimony a waste of time.

In *Daubert*, the Supreme Court seems to have inverted our view that much of Rule 403 analysis conflates into Rule 702; rather the Court seems to have conflated the confusion/overwhelming impact prong of our Rule 702 analysis into its Rule 403 analysis. The *Daubert* Court did not mention the confusion/overwhelming prong when discussing Rule 702 but did provide support for applica-

tion of essentially similar analysis under the rubric of Rule 403. The Court noted that Rule 403's balancing test of the probative against the prejudicial value of evidence has a special role in cases involving expert witnesses. It stated that because expert evidence is often more misleading than other evidence, Rule 043 gives a judge more power over experts than over lay witnesses. *See Daubert*, 113 S. Ct. at 2798. This, however, does not change our opinion that in order for a district court to exclude scientific evidence, there must be something *particularly* confusing about the scientific evidence at issue—something other than the general complexity of scientific evidence.[16]

6. Procedural concerns regarding the Rule 403/702 balancing test

In *Paoli I* we held that Rule 403 is rarely appropriate as a basis of *pre-trial* exclusion, because a judge cannot ascertain potential relevance until that judge has a virtual surrogate for a trial record. *See Paoli I*, 916 F.2d at 859-60. There, many of the district court's admissibility determinations were based in part on Rule 403; thus, it is important to determine whether the *in limine* hearing in the district court created the "virtual surrogate for a trial record" that we have required before exclusion is permissible. Plaintiffs argue that the *in limine* hearing did not create such a record because they did not have an opportunity to depose defendant's experts ahead of time. As compared with a trial, plaintiffs assert, this made it

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[16] The fact that *Daubert* held that Rule 702 is the primary locus of a court's gatekeeping role indicates that exclusion under Rule 403 should be rare despite the Court's later statement that Rule 403 gives judges greater power over experts than over ordinary witnesses. *Daubert's* view of the judges substantive power under Rule 403 is thus similar to our view of the judge's substantive power under the overwhelming/confusion prong of Rule 702—both give the judge slightly more power than is ordinarily the case under Rule 403 to find that evidence is more prejudicial than probative.

much more difficult to impeach defendants' experts and to bolster the claims of their own experts. We think that the *in limine* hearing conducted here was more than adequate as a basis for a Rule 403 determination—to hold otherwise given the extensive proceedings in the district court would be to require not a "virtual surrogate for a trial record" but a trial itself.

B. *Rule 703*

While Rule 702 focuses on an expert's methodology, Rule 703 focuses on the data underlying the expert's opinion. Under Rule 703:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Under our case law on Rule 703, "the proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be." *In re Japanese Electronic Products*, 723 F.2d at 277. *See also De Luca*, 911 F.2d at 952; *Paoli I*, 916 F.2d at 853. We have held that the district judge must make a factual finding as to what data *experts* find reliable, *see id.* at 853, and that if an expert avers that his testimony is based on a type of data on which experts reasonably rely, that is generally enough to survive the Rule 703 inquiry. *See De Luca*, 911 F.2d at 952.

This view has been rejected by other courts in favor of the view that the judge has to make an independent evaluation of the reliability of the data. *See, e.g., Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1113-14 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1280 (1992); *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159, 1161-62 (D.C. Cir.), *cert. denied*, 498 U.S. 950, 111 S. Ct. 370

(1990). As Judge Weinstein wrote in *In re "Agent Orange" Product Liability Litigation*, 611 F.Supp. 1223, 1245 (E.D.N.Y. 1985):

> Rule 703 permits experts to rely upon hearsay. The guarantee of trustworthiness is that it be of the kind normally employed by experts in the field. . . . Nevertheless, the court may not abdicate its independent responsibilities to decide if the bases meet minimum standards of reliability as a condition of admissibility. *See* Fed. R.Ev. 104(a). If the underlying data are so lacking in probative force and reliability that no reasonable expert could base an opinion on them, an opinion which rests entirely upon them must be excluded.

Judge Weinstein's view is extremely persuasive, and we are free to express our agreement with it because we think that our former view is no longer tenable in light of *Daubert*. *See Stana v. School Dist. of Pittsburgh*, 775 F.2d 122, 130 n. 8 (3d Cir. 1985) (noting that "[o]ur authority to align this court's jurisprudence with Supre Court teaching is clear."). *Daubert* makes clear for the first time at the Supreme Court level that courts have to play a gatekeeping role with regard to experts. In stating that Rule 702 is the primary locus of the gatekeeping role, the Court implies that there are at least some secondary loci in other Rules. *See Daubert*, 113 S. Ct. at 2795. By requiring the judge to look to the views of other experts rather than allowing the judge to exercise independent judgment, current Third Circuit case law eviscerates the judge's gatekeeping role with respect to an expert's data and instead gives that role to other experts. The gatekeeping role is reduced even further by our *DeLuca* holding that the opinion of one expert that a type of data is reliable will generally be enough to render that data reliable.

We now make clear that it is the judge who makes the determination of reasonable reliance, and that for the

judge to make the factual determination under Rule 104(a) that an expert is basing his or her opinion on a type of data *reasonably* relied upon by experts, the judge must conduct an independent evaluation into reasonableness. The judge can of course take into account the particular expert's opinion that experts reasonably rely on that type of data, as well as the opinions of other experts as to its reliability, but the judge can also take into account other factors he or she deems relevant.

We think that the standard is equivalent to Rule 702's reliability requirement—there must be good grounds on which to find the data reliable. It makes sense that the standards are the same, because there will often be times when both Rule 702 and Rule 703 apply.[17] For example, expert testimony that uses animal studies must, to be admissible for the purpose of drawing conclusions about humans, meet Rule 702's requirement of "fit." This requires the court to assess whether there are good grounds for concluding that the animal studies demonstrate causation in humans. But for an expert to rely on animal studies (if their admissibility in evidence is not independently established), these studies must also meet the requirements of Rule 703—the conclusions of these studies must be data which must be of a type reasonably relied upon by experts to analyze causation in humans. If the expert's reliance on animal studies to draw conclusions about people constitutes a methodological flaw, it is a methodological "flaw" *consisting of* relying on data not of a type reasonably relied upon by experts.[18] It would be prob-

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[17] Thus, the former rule that an expert's own statement is generally sufficient to meet the burdens of Rule 703 but not to meet the burdens of Rule 702 made little sense.

[18] Arguably, animal studies that an expert relies on are not his underlying data, but rather the data that went into the animal studies in the first place are his underlying data. In *Paoli I* we implied that testimony that experts did not generally rely on animal studies to draw conclusions about humans did not make that evidence unreliable for purposes of 703; rather it might make it fail

lematic to conclude that this testimony was reliable enough to meet Rule 702 but not Rule 703—or vice versa. Testimony that is admissible as reliable under one Rule should not be inadmissible under another when the policy considerations underlying the two rules are the same.[19]

We therefore think that when a trial judge analyzes whether an expert's data is of a type reasonably relied on by experts in the field, he or she should assess whether there are good grounds to rely on this data to draw the conclusion reached by the expert. Whether experts in the field rely on this type of data will simply continue to be a

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the inquiry of 702. *See Paoli I*, 916 F.2d at 854 n. 28 (noting that it is not clear whether evidence that animal studies are irrelevant to humans pertains to reliability under 703). *Cf. De Luca*, 911 F.2d at 953 (indicating that a proper challenge to a method of statistical analysis that did not require a .05 level of statistical significance arose out of Rule 702 not out of Rule 703—the data was of the type reasonably relied on by experts because the data underlying the analysis was acceptable. This was true even if the methodology was questionable and even if relying on the data produced by the study to draw conclusions was questionable).

However, even if Rule 702 and Rule 703 never apply to the same admissibility question, we think the same reliability standard should apply under both rules because the policy considerations are the same. Moreover, applying the same standard avoids the need to make the metaphysical distinctions necessary to decide which rule applies. *See Paoli I*, 916 F.2d at 856 ("it can be difficult to determine whether the putative problem with scientific evidence lies in the underlying data itself or the method by which the data is analyzed.").

[19] This does not make the two rules redundant. There will be times when an expert's methodology is generally reliable but some of the underlying data is not of a type reasonably relied on by experts. In those cases, the expert can testify so long as he or she does not significantly rely on the unreliable data, and so long as his or her testimony survives Rule 702 without any reliance on the excluded data. Moreover, if the judge thinks that the expert would reach a different conclusion if he was not able to rely on this data, a conclusion that would no longer help the plaintiff (or defendant) to prove his or her case, the district court can exclude his opinion as irrelevant.

part of the judge's analysis. After all, the only purpose of Rule 703 was to supplant the (former) common law rule that experts could *not* (reasonably) rely on inadmissible evidence, a notion demonstrated by the Rule 703 advisory committee to be contrary to real life.

C. *Standard of Review*

A district court's ruling on admissibility of evidence is reviewed for abuse of discretion, "but to the extent the district court's ruling turns on an interpretation of a Federal Rule of Evidence our review is plenary." *De Luca*, 911 F.2d at 944. The threshold rule is, of course, one of deference. However:

> the justifications for committing decisions to the discretion of the court are not uniform, and may vary with the specific type of decisions. Although the standard of review in such instances is generally framed as "abuse of discretion," in fact the scope of review will be directly related to the reason why that category or type of decision is committed to the trial court's discretion in the first instance.

United States v. Criden, 648 F.2d 814, 817 (3d Cir. 1981). In several other areas, we have applied a heightened abuse of discretion review. *See, e.g., Brody v. Spang*, 957 F.2d 1108, 1115 (3d Cir. 1992) ("We review a denial of a motion to intervene as of right for abuse of discretion, although this review is 'more stringent' than the abuse of discretion review we apply to a denial of a motion for permissive intervention"); *Harris v. Pernsley*, 820 F.2d 592, 597 (3d Cir.), *cert. denied*, 484 U.S. 947, 108 S. Ct. 336 (1987). Under the *Harris* standard, a denial of intervention as of right should be reversed if the district court applied an improper legal standard or reached a decision that we are confident is incorrect." (internal quotation omitted)); *United States v. Miele*, 589 F.2d 659, 667 (3d Cir. 1993) (looking rigorously to see whether the district court had closely scrutinized drug

quantity when the court based its decision on the statements of an addict-informant); *cf. Malchman v. Davis*, 706 F.2d 426, 434 (2d Cir. 1983) (holding that while a court of appeals normally reviews a class action settlement for abuse of discretion "this principle [of deference] applies with less force when, as here, settlement of a class action has been negotiated before the class has been certified.").

While evidentiary rulings are generally subject to a particularly high level of deference because the trial court has a superior vantage point to assess the evidence, *see Criden*, 648 F.2d at 818, evaluating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses and thus is often not significantly more difficult on a cold record. Moreover, here there are factors that counsel in favor of a hard look at (more stringent review of) the district court's exercise of discretion. For example, because the reliability standard of Rule 702 and 703 is somewhat amorphous, there is a significant risk that district judges will set the threshold too high and will in fact force plaintiffs to prove their case twice. Reducing this risk is particularly important because the Federal Rules of Evidence display a preference for admissibility.[20] *See Daubert*, 113 S. Ct. at 2794.

Factors like those just discussed influence the scope of our review of a district court's discretion. For example, where rules display a preference for a particular outcome, our review of decisions under those rules is sometimes more searching. *See United States v. Pennsylvania Department of Envir't Resources*, 923 F.2d 1071, 1074 (3d Cir. 1991) ("[T]he traditional discretion of the federal courts to decide whether to hear declaratory judgment cases is not limited by *Colorado River* and *Moses H.*

[20] Indeed, a similar gloss may be gleaned from the Seventh Amendment's guarantee of a right to a jury trial when a party with a legal claim demands one.

Cone, but will be subject to the liberal interpretation to be accorded the Declaratory Judgment Act. Given our correspondingly enlarged scope of review . . ., the district court's declination to exercise jurisdiction . . . is not consistent with a sound exercise of judicial discretion." (internal quotation omitted)). Moreover, the likelihood of finding an abuse of discretion is affected by the importance of the district court's decision to the outcome of the case and the effect it will have on important rights. *See Maroquin-Manriquez v. Immigration and Naturalization Service*, 699 F.2d 129, 134 (3d Cir. 1983) (abuse of discretion will only be found in discovery if there has been interference with a substantial right or fundamental unfairness at the trial has resulted.); *cf. Mathews v. Eldridge*, 424 U.S. 319, 334, 96 S. Ct. 893, 902 (1976) (the procedural safeguards required by due process increase as the importance of the decision being made increases).

We acknowledge that there is arguably a tension between the substantial deference normally accorded to rulings where the trial court has a superior vantage point and the preference for admissibility of the Federal Rules of Evidence. We resolve any such tension by holding that when the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a "hard look" (more stringent review, *cf. Brody v. Spang*, 957 F.2d at 1115) to determine if a district court has abused its discretion in excluding evidence as unreliable.[21]

D. *The Role of Pennsylvania's Requirement of Reasonable Medical Certainty*

Pennsylvania requires experts to testify that defendant's actions caused plaintiff's illness with a reasonable degree

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[21] Of course, it remains true that if the scintilla of evidence presented is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, *see* Fed. R. Civ. P. 50(a), and likewise to grant summary judgment, Fed. R. Civ. P. 56.

of medical certainty, *see Cohen v. Albert Einstein Medical Ctr.*, 592 A.2d 720, 724 (Pa.Super. 1991), *appeal denied*, 602 A.2d 855 (Pa. 1992) ("Expert testimony is admissible when, taken in its entirety, it expresses reasonable certainty that the accident was a substantial factor in bringing about that injury. The expert need not express his opinion in precisely the same language we use to enunciate the legal standard.") (quoting *Kravinsky v. Glover*, 396 A.2d 1349 (Pa. Super. 1979) (citation within *Kravinsky* omitted). The issues presented by this appeal require us to determine whether this rule governs in federal court. Because it will facilitate our discussion of the individual evidentiary rulings if we do so in the earlier portions of the opinion, we turn our attention to the question now.

If the rule conflicts with federal rules and is "rationally capable of classification" as procedural rather than substantive, then, as a federal court, the district court ignores the rule and applies federal rules instead. *See Hanna v. Plumer*, 380 U.S. 460, 472, 85 S. Ct. 1136, 1144 (1965). But "the determination of whether a particular evidentiary ruling involves federal procedural law or state substantive law, can be difficult. Often admissibility issues overlap with substantive concerns such as standards of proof." *Schulz v. Celotex Corp.*, 942 F.2d 204, 207 (3d Cir. 1991).

In *Schulz*, we refrained from deciding whether New Jersey's requirement that a medical expert testify with "reasonable medical certainty" was procedural or substantive, because we held that the federal rules, like the New Jersey rules, also required that, at a minimum, a physician be able to "form an opinion with sufficient certainty so as to make a medical judgment," *id.* at 209, and that this was enough to decide the particular case. Thus, while *Schulz* did not require the specific words "reasonable degree of medical certainty," testimony about "possibilities" or even "strong possibilities" was not admissible (though testimony made without qualifications was admissible).

Id. at 208. The issue is framed here primarily by an instance in which Dr. Sherman stated her conclusion with more certainty than a "strong possibility" (she stated that PCBs were a "significant factor" in Amber Burrell's diminished ankle reflexes) but was unwilling to testify that she had reached that conclusion with a reasonable degree of medical certainty. (The issue also arises with respect to other pieces of evidence.) Thus, we must decide whether experts were required to testify with a reasonable degree of medical certainty.

We conclude that they were. Although if it were purely a rule of admissibility Pennsylvania's standard would not apply in federal court. Pennsylvania's rule also constitutes part of the plaintiff's burden of proof. As a rule of admissibility, Pennsylvania's standard is in conflict with Rules 702 and 703 which require a reasonable degree of medical certainty. *See United States v. Cyphers*, 553 F.2d 1064, 1072 (7th Cir.), *cert. denied*, 434 U.S. 843, 98 S. Ct. 142 (1977) upholding a district court's admission of expert testimony that was not based on reasonable scientific certainty); *cf. Daubert*, 113 S. Ct. at 2794 (holding that the *Frye* rule requiring a methodology to be generally accepted was not part of the Federal Rules of Evidence); *but see Grant v. Farnsworth*, 869 F.2d 1149 (8th Cir. 1989), *cert. denied*, 493 U.S. 898, 110 S. Ct. 252 (1989) (upholding the district court's exclusion of expert testimony where a chiropractor could not state the causes of plaintiff's disability with a reasonable degree of medical certainty).

If Pennsylvania's rule were only a standard of admissibility in conflict with Federal Rules of Evidence, Pennsylvania's rule would be "rationally capable of classification as procedural" and the Federal Rules of Evidence would govern. *See, e.g., Salas v. Wang*, 846 F.2d 897, 904-06 (3d Cir. 1988) (holding that under the Federal Rules of Evidence, an expert could testify to aggregate

damages and that this rule was procedural, thus trumping New Jersey's opposite rule). However, we think that Pennsylvania's rule is more than a requirement of admissibility, but rather it is an element of plaintiff's burden of proof. In *Cohen,* the Pennsylvania Superior Court stated that:

> When a party must prove causation through expert testimony the expert must testify with reasonable certainty that in his professional opinion, the result in question did come from the cause alleged . . . [I]f the plaintiff's . . . expert cannot form an opinion with sufficient certainty so as to make a [professional] judgment, there is nothing on the record with which a [factfinder] can make a decision with sufficient certainty so as to make a legal judgment.

Cohen, 692 A.2d at 723 (quoting *Kravinsky v. Glover,* 396 A.2d 1349 (Pa. Super. 1979)) (internal quotations omitted). Thus, the *Cohen* court strongly implied that, even if admissible, testimony with less than a reasonable degree of medical certainty was insufficient to prove causation. *See also id.* (stating that this was "[t]he degree of medical certainty necessary to prove causation.").

As part of the burden of proof, then, Pennsylvania's rule is a substantive one, not in conflict with Federal Rules of Evidence, and thus governs in federal court. *See, e.g., Herber v. Johns-Manville Corp.,* 785 F.2d 79, 81-82 (3d Cir. 1986) (holding that New Jersey's requirement that a plaintiff must show a "reasonable medical probability" of future injury in order to recover for that injury governed in federal court). As a result, in analyzing the testimony of Dr. Sherman and other witnesses with respect to particular plaintiffs, we will uphold the district court's grant of summary judgment for the defendants in those instances when the plaintiffs' expert states that he or she could not testify that a plaintiff's illness was caused by PCBs with a reasonable degree of

medical certainty. We turn to application of the foregoing principles to the record in this case.

VI. THE RELATIONSHIP BETWEEN PCBs AND PLAINTIFFS' ILLNESSES

In order to sustain their traditional tort claims, i.e. other than for medical monitoring, the personal injury plaintiffs must show that they were exposed to the chemicals released by the defendants, that these chemicals can cause the types of harm they suffered, and that the chemicals in fact did cause them harm. We begin our analysis at the last step, because this is the step at which it is easier to winnow the claims on which the plaintiffs have presented admissible testimony.

Eleven of the Kohn/Klehr plaintiffs offered Janette D. Sherman, M.D. as an expert in internal medicine and toxicology. They proposed to have Dr. Sherman testify: (1) that they had been exposed to PCBs and other toxic chemicals; (2) that the toxic chemicals had caused adverse health effects in the various plaintiffs including high blood pressure, lung disease, asthma, elevated triglycerides, aortic sclerosis and eventual death, arthritis, respiratory infections and a history of miscarriages; and (3) that exposure to these chemicals poses an increased risk for various plaintiffs of developing cancer or other illnesses in the future. These plaintiffs also proffered Dr. Sherman to show that they require regular medical monitoring. The district court excluded Dr. Sherman's testimony holding that she lacked the requisite expertise, that her methodology was unreliable, and that the probative value of her testimony was substantially outweighed by unfair prejudice and undue delay.

Nine plaintiffs, those represented by Bruce Hanes, called Dr. G. John DiGregorio to testify that the plaintiffs' present injuries were caused by PCB exposure, that they have an increased and reasonable fear of future injuries, and that a medical monitoring program, which Dr. Di-

Gregorio would design, should be implemented for plaintiffs. (A2634-35). Dr. DiGregorio received both a Ph.D. in pharmacology and an M.D. from Hahnemann Medical College and is a professor in pharmacology and medicine at Hahnemann. The district court accepted Dr. DiGregorio as a qualified expert but excluded his testimony regarding personal injuries as unreliable.

We will begin our analysis by evaluating Dr. Sherman's qualifications and will reverse the district court's exclusion of Dr. Sherman as an unqualified expert. We will next briefly examine the district court's exclusion of the immunological tests relied on by Dr. Sherman for some of her diagnoses and will uphold that exclusion. We will then discuss the defendants' claims that Drs. Sherman and DiGregorio engaged in too few of the standard diagnostic techniques of "differential diagnosis," and failed seriously to consider the possibility of alternative causes of plaintiffs' illnesses other than exposure to PCBs. After describing the critique, we will apply *Daubert* to analyze generally what makes a doctor's method of differential diagnosis so unreliable as to be within the district court's power to exclude it. We will then apply this framework to the assessment of individual plaintiffs that Dr. DiGregorio and Dr. Sherman made. We will uphold the district court's exclusion of the testimony of Dr. Sherman and Dr. DiGregorio for the assessment of present injuries with the exception of Dr. Sherman's testimony regarding Bessie Cunningham and Amber Burrell.

A. *Dr. Sherman's Qualifications*

Dr. Sherman is a 1964 graduate of the Wayne State University School of Medicine. Following a one year internship at Wayne State University Hospital and a two year fellowship funded by the National Institutes of Health to study diabetes, she practiced internal medicine full time from 1970-76. Since that time she has apparently been engaged in the full time practice of forensic medicine. Dr.

Sherman is the author of 22 articles and of the book *Chemical Exposure and Disease—Diagnostic and Investigative Techniques.* She served for six years on a 16 person advisory committee to the EPA that was convened in connection with the adoption of the Toxic Substance Control Act—an Act largely concerned with PCBs. She was on the consulting staff of Harper Hospital in Detroit until 1988 and is still on its correspondence staff. A. 5086-87.

The district court held that Dr. Sherman was not qualified to testify as an expert. It explained that Dr. Sherman no longer practices general internal medicine—she does not have admitting privileges at any hospital and lacks an office where she can examine patients. Since 1976 most of her work has consisted of consulting for litigation; she has been involved in 800 cases and has been on the plaintiffs side in all but two. According to the district court, out of fifty patients she has examined who have been exposed to PCBs, she cannot remember one instance in which she found that PCBs had not caused adverse health effects. A. 5124.

Moreover, the district court noted, Dr. Sherman lacks board certification in any medical specialty including internal medicine and toxicology, and admits that she is not an expert in immunology, oncology, neurology, psychiatry, dermatology, epidemiology or exposure assessment. Although Dr. Sherman represents that she became an expert in toxicology through experience, reading, writing, teaching, evaluating patients and course work, she took no courses on toxicology in medical school, and the district court concluded that it did not observe anything in her testimony to indicate that her reading was of a serious naure.

Finally, the district court credited defendants' witnesses who testified that, during the course of her testimony, Dr. Sherman made numerous basic medical errors in the fields of immunology, internal medicine and dermatology. The court referred to several examples cited by defendants' ex-

perts. Dr. Jordan Fink, Professor of Medicine and Chief of the Allergy Immunology Division at the Medical College of Wisconsin, testified that Dr. Sherman incorrectly excluded essential hypertension, the name for the 80% of hypertension with an unknown cause, from her list of the causes of hypertension, incorrectly stated that cells in the immune system transport skin pigment cells, and referred to "myelin cells" which do not exist. Dr. James Leyden, a professor at the University of Pennsylvania Medical School, who has twice won the gold medal from the American Academy of Dermatology, stated that Dr. Sherman incorrectly asserted that one could not distinguish between chloracne and acne based on their appearance—a distinction which, in his view, any qualified dermatologist could easily make. Drs. Michael Weitekamp, Robert Morgan and Paul Roediger pointed out similar errors in Dr. Sherman's testimony. And Dr. Fink concluded that these gaps in knowledge were "major deficits. They—these items should be right in the forefront of knowledge of any internist, any resident, any medical student." The district court concluded that these "major deficits" removed Dr. Sherman from the category of expert.

We disagree. We hold that Dr. Sherman, while arguably a relatively poor clinician and less than fully credible witness, qualifies as an expert. She was on the consulting staff of a hospital until she moved from Michigan in 1988. Since then she has had extremely broad experience in the field of toxic substances, has written extensively in the field and has consulted for the American Legion Science Panel—a group of experts analyzing scientific issues, such as dioxin poisoning, that effect veterans. The fact that most of her work since 1976 has been for plaintiffs in litigation may undermine her credibility but does not eradicate her expertise. For litigants to have access to experts, it may be necessary for some experts to concentrate on litigation.

Dr. Sherman apparently made substantive mistakes in her testimony, but that testimony also demonstrated sig-

nificant familiarity with the literature on PCBs; indeed her testimony in that area, which is central to this case, was not substantially challenged. Of course, Dr. Sherman was not merely testifying about PCBs but about the relation of PCBs to diseases in particular plaintiffs. In order to testify about this relationship, she needed to know about the various diseases, and it is mostly in this area that she made mistakes. But in a deposition lasting four days, it is hardly surprising that there were a few technical errors. Indeed, many of Dr. Sherman's mistakes seem minor and unlikely to affect her ability to express an opinion (e.g. use of the word "thymus" instead of "thyroid," use of the terms "myelin cells" instead of "myelin containing cells").

Others of Dr. Sherman's "mistakes" are hard to judge. For example, her reference to the movement of skin pigment referred to pigment that developed in nails and skin as a result of exposure to PCBs rather than to general skin pigment (A791, A5114)—and whether this type of pigment moves is unclear. However, some of the mistakes Dr. Sherman made, such as her contention that acne and chloracne look the same, seem significant for diagnostic purposes.[22] Moreover, the number of mistakes she made was quite significant.

Nonetheless, the mistakes Dr. Sherman made do not render her unqualified as an expert for purposes of Rule 702. If the liberal standard of Rule 702 allows an engi-

[22] Plaintiffs contend that Dr. Sherman's alleged claim that acne and chloracne look the same arise from a misreading of her testimony. In their submission, Dr. Sherman was testifying only that the precursors of chloracne might look the same as acne, and because defendants' expert had not ever seen the precursors to chloracne, he was in no position to say she was wrong. As we see it, this contention is specious, for Dr. Leyden, a renowned expert on dermatology, testified that he had never seen chloracne in anything but a full blown form and strongly implied that this was the only visible form. But he also admitted that many internists probably could not tell the difference between chloracne and acne. A 4954. And Dr. Weitekamp, one of defendants' experts, stated that he could not distinguish chloracne and acne. A4296.

neer who teaches auto mechanics to testify in a products liability action about tractors, *see Hammond v. Int'l Harvester Co.*, 691 F.2d 646 (3d Cir. 1982), *supra* at p. 40, it surely allows a trained internist who has spent significant time reviewing the literature on PCBs to testify as to whether PCBs caused illness in plaintiffs. In light of *Hammond,* Rule 702 does not require plaintiffs to hire separate experts on the relationship between PCBs and diabetes, PCBs and chloracne, PCBs and cancer etc.; it is likely that none such exist, and the cost would be prohibitive. Under our liberal standards for qualifications of experts, the district court's decision that Dr. Sherman was not a qualified expert was an abuse of discretion.

B. *Rule 703 and Dr. Sherman's Immunological Tests*

The district court also held that some of the data on which Dr. Sherman relied, immunological test results from a chemical injury kit, were not the type of data reasonably relied upon by experts in the field under Rule 703. The district court based its holding on the fact that the lab work was performed by an unaccredited laboratory and the fact that two of defendants' experts testified that the tests were not important, would probably be more misleading than helpful, and had been misinterpreted. Plaintiffs cite Dr. Sherman's testimony for the proposition that she did not rely on these tests. Defendants respond that these tests were often the *only* basis she cited for her conclusion that PCBs had caused plaintiffs' injuries.

We will analyze the importance of the tests to Dr. Sherman's testimony when we analyze her testimony with respect to the particular plaintiffs. *See supra* p. 54 n. 19 (explaining what a court should do when an expert testifies based in part on data deemed unreliable under Rule 703). However, since the plaintiffs do not defend the tests themselves, there is no real dispute that they may not be the basis for any of Dr. Sherman's conclusions. If Dr. Sherman is allowed to testify, she will not be allowed to rely on these tests.

C. *Adequacy of Dr. Sherman's and Dr. DiGregorio's Use of Differential Diagnosis in Evaluating Causation of Present Illnesses*

1. The district court's critique

The district court also excluded Dr. Sherman's testimony under the helpfulness prong of Rule 702. It believed defendants' seven witnesses who opined that Dr. Sherman did not employ differential diagnosis, the basic method of internal medicine. Dr. Fink testified that an internist should inquire of the patient about his or her complaint(s), the history of the complaint(s), any other illnesses the patient might have, the patient's occupation, and habits such as smoking. In his view, the internist should then use differential diagnosis to rule out possible alternative diseases and causes of these diseases by outlining the possibilities and then narrowing them down based on the doctor's experience. For example, even if plaintiffs were exposed to PCBs and PCBs are dangerous, a doctor employing proper methodology could not conclude that PCBs were a substantial factor in the cause of an illness without thinking about other potential causes.

More particularly, according to Dr. Fink, before a doctor could reasonably conclude that PCBs contributed to an individual's lung cancer, she would have to ask whether the individual was a smoker, and if that individual was a smoker, she would have to take steps to determine whether the individual's lung cancer was more consistent with exposure to smoking or PCB exposure or both. She would also have to consider the history of the person's exposure to both PCBs and cigarettes, and would have to perform laboratory tests and physical examinations to determine the likely cause(s).

According to the district court, Dr. Sherman failed to employ any of the ordinary methods doctors use to narrow down the cause of disease. She did not order standard laboratory tests to be performed on plaintiffs (ordering

only unhelpful immunological tests from an unaccredited laboratory), physically examined only two of the thirteen plaintiffs about whom she offered opinions,[23] and took medical histories only from the two plaintiffs she examined physically.[24] The district court noted that Dr. Fink testified that it is standard medical practice to take medical histories and conduct physical examinations, and that it would not be appropriate to base a patient's care solely on medical records from the patient's prior physicians. Similarly, Dr. Weitekamp testified that without going through the entire process outlined above, it is difficult to make a

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[23] In their briefs, plaintiffs state that Dr. Sherman examined three of them. But in the supplemental materials that the plaintiffs sent to us detaiilng the evidence presented by each plaintiff, there is only evidence that Dr. Sherman examined two plaintiffs.

[24] Dr. Sherman had not examined any of the plaintiffs by the March 2, 1992, deadline for completition of discovery. The plaintiffs asked for an extension of discovery to allow Dr. Sherman, who had been in Hawaii from December 1991 to April 1992, to examine them. (A498-99). On April 8, 1992, defendants wrote to the district court requesting that Dr. Sherman be required to complete medical examinations on or before April 23 (A526-27). Plaintiffs agreed to the defendant's proposed April 23 deadline (A 529) and Dr. Sherman examined some of the plaintiffs by that time. On April 24th the Clerk of the Court entered an order refusing to extend the discovery deadline and precluding Dr. Sherman from taking examinations of any of the plaintiffs.

Plaintiffs contend that the district court's order was unfair, and explains Dr. Sherman's failure to examine more of the plaintiffs. However, plaintiffs neither reference the district court's ruling in their notice of appeal nor list this ruling in their brief as an issue on appeal. Thus, plaintiffs are merely attempting to use this district court order as a means to make Dr. Sherman's failure to examine all plaintiffs appear reasonable. But it was plaintiffs who failed to comply with the district court's reasonable order. At all events, if Dr. Sherman's failure to examine patients makes her methodology unreliable, it does so regardless of whether the cause of that failure was externally imposed. Moreover, as plaintiffs acknowledge, they agreed that Dr. Sherman would conduct all physical exams by April 23, 1992, and they received until April 24 to conduct these exams.

complete diagnosis, and that Dr. Sherman did not perform a differential diagnosis.

The district court also relied on the fact that Dr. Sherman did not even consider alternative causes for various diseases. The court pointed to the testimony of Dr. Fink and Dr. Roediger, both of whom implied that the real problem with Dr. Sherman's methodology was not that she was unaware of possible alternative causes but that she did not *really* consider them.[25] Defendants note that, despite her testimony that she had employed differential diagnosis and had considered alternative causes. when asked about specific findings of causation. Dr. Sherman acknowledged that she had not looked at nor ruled out alternative causes for plaintiffs' illnesses including high blood pressure, stomach cancer, asthma, episcleritis or anemia. Moreover, Dr. Roediger tesitfied that, "I do not feel that the concept of ruling out the commonest causes of diseases was ever displayed in her testimony in a fashion that would portray her as a competent internist." This was because she did not give evidence of having considered the common causes of many of the diseases she diagnosed. On this basis, the district court held that Dr. Sherman's methodology was unreliable.

For similar reasons, the district court excluded the testimony of Dr. DiGregorio. In some ways Dr. DiGregorio's methodology was more complete than was Dr. Sherman's. He took a limited medical history of each plaintiff—asking about their family medical history. He also had a blood test and a fat biopsy performed on each plaintiff to test for PCBs. Nonetheless, in other ways Dr. DiGregorio's analysis was more limited than that of

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[25] Although plaintiffs argue that Dr. Fink conceded that he did not know what Dr. Sherman's methodology was (A4883-4884), which they say means he could not judge it, in actually Dr. Fink was saying that there was no evidence that she had employed *any* methodology, and no evidence that she really considered any alternative causes. (A4867, A4883).

Dr. Sherman. Dr. DiGregorio did not even look at medical records of the plaintiffs much less examine them. With selective exceptions, Dr. DiGregorio's methodology was to have each plaintiff mark their symptoms on a checklist, answer questions about their family medical history, discuss the answers they had given on the checklist, and obtain blood and fat samples to be tested for PCBs.

The district court applied the testimony offered by defendants about Dr. Sherman to the methodology of Dr. DiGregorio.[26] It found that differential diagnosis which is used to rule in or out alternative causes is the "hallmark" of internal medicine and that Dr. DiGregorio had not employed it. The court found that Dr. DiGregorio had intended to use differential diagnosis but had not performed the examinations and tests that he as well as defendants' experts thought were necessary to render

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[26] Plaintiffs argue that until August 6, 1992 they had no notice that defendants intended to challenge Dr. DiGregorio's methodology with testimony directed at Dr. Sherman. They contend that this late notice was fundamentally unfair. In the absence of this testimony, specific application of the testimony directed at Dr. Sherman to Dr. DiGregorio, or other testimony indicating that Dr. DiGregorio's methodology was unreliable, plaintiffs submit that defendants were not even entitled to a hearing on whether the testimony should be excluded. We think that the defendants are right that the district court was fair in viewing the testimony of defendants' experts as addressing Dr. DiGregorio's methodology as well as Dr. Sherman's methodology. The Hanes plaintiffs expressly relied on the testimony of the Kohn plaintiffs' experts as part of their case and thus had reason to be aware of challenges to Dr. Sherman's methodology and of the fact that it would apply equally to the testimony of their own expert. Moreover, the district court pointed to the testimony of Dr. DiGregorio himself as showing that his methodology was unreliable and, as defendants note, Dr. DiGregorio's methodology was condemned in affidavits in 1988 and was criticized in Dr. Weitekamp's deposition in 1992 (A6968-75); Dr. DiGregorio was asked about his methodology at length during his 1992 deposition (A3089-3149). Thus plaintiffs' contention is without merit.

"a correct, final diagnosis." The court found that Dr. DiGregorio admitted that, until he physically examined plaintiffs, he would not even be able to know if they suffered any injuries caused by PCBs. Yet Dr. DiGregorio did not perform these tests or examinations in the four years between his 1988 deposition and his 1992 deposition, although he had testified in 1988 that he planned to perform these tests and exams and that they could be completed in six months.

According to the district court, Dr. DiGregorio's failure to perform these tests not only left him with little information about plaintiffs' actual injuries, it left him with little information about causation. The court cited examples of Dr. DiGregorio being unaware of activities engaged in by plaintiffs that were possible alternative causes of their injuries, such as excessive alcoholic drinking as an alternate cause of Craig Brown's elevated LDH, and taking the birth control pill Ortho-Novum as an alternate cause of Cathlene Brown's bruising. The court observed that Dr. DiGregorio had simply concluded that all of the plaintiffs' symptoms were caused by exposure to PCBs "until proven otherwise."

As a result of the foregoing, the court found that Dr. DiGregorio's methodology was incomplete and therefore would not be helpful to the jury under Rule 702. In the court's view, by failing to consider alternative causes, Dr. DiGregorio's testimony would force the jury arbitrarily to choose one cause from many possible causes and, because Dr. DiGregorio did not examine plaintiffs' to determine that they actually had injuries, his methodology was rendered incomplete and unreliable. Finally, because Dr. DiGregorio failed to perform physical exams or many tests, the court determined that the type of data he relied on was not a type experts reasonably rely on under Rule 703. It noted in conclusion that "[t]he only opinion that Dr. DiGregorio is consistent in holding throughout his deposition is that the Plaintiffs' anxiety, fear of cancer,

depression and abnormal lab values were caused by exposure to PCBs."

2. The plaintiffs' response

The plaintiffs' attempt to revive the methodologies of Drs. Sherman and DiGregorio by arguing that the requirements of differential diagnosis are not nearly as rigorous as the district court found them to be. Plaintiffs point out that Dr. Sherman testified in the *in limine* hearing that she had used differential diagnosis since she was in medical school, and that she had done so here even with regard to those plaintiffs whom she did not examine. More particularly, she looked at medical records, which contained the results of physical exams performed by other physicians (and medical histories taken by other physicians), and at illnesses across the population, and then applied the medical literature to narrow down the cause. Dr. Sherman also testified that she *did* consider possible alternative causes before reaching her conclusions.

Similarly, while it is true that Dr. DiGregorio testified that in order to render a final opinion he would have to perform more tests, he also testified that, absent further evidence, he had enough information to conclude with a reasonable degree of medical certainty that PCBs were the cause of plaintiffs illnesses. He explained:

> When a doctor does a history and there's a cause of a problem, whether it's pneumonia, pulmonary tract infection, the differential diagnosis—the leading differential diagnosis at the time is what the doctor suspects is the immediate cause of the problem. And it's up to the doctor to proceed after that point and to prove either by physical examination or more tests whether his diagnosis is correct. So, as far as I'm concerned the symptoms that these patients gave me in the history are due to PCB exposure. Until I have the opportunity to continue on with my investigation

> they all will have, within a reasonable degree of medical certainty, that type of symptom.

Thus, he concluded, at least as a preliminary manner, that until performance of physical exams or more tests, PCBs were the cause of plaintiffs' illnesses. And in reaching this conclusion, he stated that he followed normal methodology—"[t]he differential diagnosis you make with whatever information you have at the time. What you do now is to prove your diagnosis."

In essence, plaintiffs' argument is that what Dr. DiGregorio was saying was that differential diagnosis is an ongoing process of making judgments about causation and then adapting those judgments as new information is acquired. Dr. DiGregorio then, was asserting that, when he made his "preliminary" differential diagnosis, he had sufficient information (his knowledge of plaintiffs' exposure to PCBs, his knowledge of the effects of PCBs, and the medical histories he took) reliably to conclude that PCBs were more likely than not a cause of plaintiffs' illnesses even after considering other possibilities. Thus, the question becomes whether the district court abused its discretion in concluding that Dr. Sherman and Dr. DiGregorio's methodology of assessing causation was unreliable because of the limited information they had gathered.

3. Rule 702 Analysis

The defense experts' criticisms of the methodologies of Drs. Sherman and DiGregorio were specific criticisms of the manner in which they each engaged in differential diagnosis (to the point where they asserted that Drs. Sherman and DiGregorio had not even employed differential diagnosis). Unfortunately, most of the *Daubert* factors—testability, general acceptance, peer review, and degree of production of errors, *see supra* at 42 n. 8, are of only limited help in assessing whether the methodologies of Drs. Sherman and DiGregorio are reliable (i.e. scientifically valid). We find that the final *Daubert* factor, the

existence of standards controlling the technique's operation, is slightly more helpful in deciding whether the methodologies of the plaintiffs' doctors are reliable.

While applying the first *Daubert* factor, differential diagnosis can be considered to involve the testing of a falsifiable hypothesis (e.g. that PCBs caused a plaintiff's cancer) through an attempt to rule out alternative causes, that methodology involves far more elements of judgment than does a scientific study attempting to test a more general scientific proposition. While an important aspect of assessing scientific validity (and therefore evidentiary reliability) is the ability of other scientists to test or retest a proponent's theory, differential diagnosis involves assessing causation with respect to a particular individual. This merely makes it a different type of science than science designed to produce general theories; it does not make it unreliable science. Although in terms of the remaining *Daubert* factors, differential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results, it is a method that involves assessing causation with respect to a particular individual. As a result, the steps a doctor has to take to make that (differential) diagnosis reliable are likely to vary from case to case; the information a doctor needs in order to reliably assess the cause of a patient's lung cancer is often very different from the information neeeded to assess the cause of a patient's back or heart trouble.

Thus, although differential diagnosis is a generally accepted technique, no particular combination of techniques chosen by a doctor to assess an individual patient is likely to have been generally accepted. But unlike a methodology used in conducting a scientific study, lack of general acceptance is not a sign of unreliability, it is merely a result of the fact that the medical community will rarely have considered the reliability of a particular process of differential diagnosis used in an individual case. Nor is it

likely that the particular combination will have been published and subject to peer review, because a particular version of differential diagnosis will rarely be of general interest to the medical community. However, to the extent that a doctor utilizes standard diagnostic techniques in gathering this information, the more likely we are to find that the doctor's methodology is reliable. For these reasons, we must be flexible in conducting our *Daubert* inquiry.

We first note that defendants presented evidence that the methodologies of Drs. Sherman and DiGregorio were not generally accepted. Defendants' experts explained that a reliable differential diagnosis generally requires a physical examination of the patient, a review of medical records, and always requires careful consideration of alternative causes. We agree with the defendants that performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence makes it much less likely that a differential diagnosis is reliable.[27] We reach this con-

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[27] Precedent supports our conclusion that when a doctor employs standard diagnostic techniques, his or her testimony is much more readily admissible. In *Hines v. Consolidated Rail Corp.*, 926 F.2d 262 (3d Cir. 1991), we considered the claims of a railroad worker who asserted that his diseases were caused by PCBs at the railyard. After the defendants challenged internist Dr. Harry Shubin's data and methodology as inadequate because he did not point to epidemiological studies demonstrating that PCBs caused cancer, and the plaintiff's blood level did not demonstrate the presence of PCBs above background levels, the district court excluded the testimony without an opinion or an *in limine* hearing. We reversed. While relying partly on the district court's failure to grant adequate process and partly on the low liability standard of the Federal Employers' Liability Act, 45 U.S.C. §§ 51-60, we indicated that "Shubin's intensive and personal investigation of Hines distinguishes Shubin's testimony from the testimony excluded by courts in a number of cases cited by Conrail where there was no evidence in the record that experts ever examined or tested the plaintiff (or assertions) at issue." *Id.* at 271. We observed that:

clusion in part based on the persuasive testimony of defendants' experts that these techniques are generally accepted as a standard part of differential diagnosis, and that such techniques significantly reduce the likelihood of erroneous results. We also base our conclusion on the fact that all of the experts agree that at the core of differential diagnosis is a requirement that experts at least consider alternative causes—this almost has to be true of any technique that tries to find a cause of something. Moreover, performance of standard diagnostic techniques provides prima facie evidence that a doctor has considered such causes and has attempted to test his or her initial hypothesis as to cause.

But, we agree with the plaintiffs that a doctor does not always have to employ all of these techniques in order for the doctor's differential diagnosis to be reliable. Dr.

> Shubin used traditional methods to form his opinion by reviewing a variety of background factors that are normally investigated in the medical profession, including Hines' histories of other exposures to toxins, drugs, and alcohol, the length of his residences, employment experience, PCB-related symptoms, blood tests, liver function tests, immunological tests, gas chromatograph tracings, a number of reports as well as all of the scientific literature that indicates that PCBs can be associated with severe health problems, including cancer.

Id. at 274.

It could be argued that, under *Hines*, the testimony of a doctor who engages in the traditional techniques of differential dianosis is admissible regardless of whether he offers a plausible explanation of the conclusion he reaches. We admitted Shubin's testimony because "even though Shubin's opinion [that PCBs caused plaintiff's illnesses] could be considered 'novel,' it appears that, under the *Downing* standard, his methods were not." *Id.* However, while we think that the standard techniques of differential diagnosis are reliable and will allow a doctor who employs them to testify to a novel conclusion, we also think that part of differential diagnosis is using these standard techniques to rule out alternative causes—thus, where a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.

DiGregorio testified that in reaching his conclusions, he followed normal methodology—"[t]he differential diagnosis you make with whatever information you have at the time." What Dr. DiGregorio was saying was that differential diagnosis is an ongoing process of making judgments about causation and then adapting those judgments as new information is acquired. He was asserting that even without examining the plaintiffs or conducting laboratory tests, he had sufficient information (his knowledge of plaintiffs' exposure to PCBs, his knowledge of the effects of PCBs, and the medical histories he took) to reliably conclude that PCBs were more likely than not a cause of plaintiffs' illnesses even after considering other possibilities.[28]

Put differently, we agree with the view of Drs. Sherman and DiGregorio that sometimes differential diagnosis can be reliable with less than full information, and, to the extent that the district court concluded otherwise, we hold that it abused its discretion. To provide a simplistic example, imagine a patient who comes in wtih medical records that include x-rays showing a fractured arm and who tells the doctor that he hurt the arm in a biking accident; the doctor could reliably conclude that the patient had a fractured arm caused by a biking accident even without physically examining the patient or taking a medical history.[29] The biking accident is so much more likely to have been the cause of the fracture than anything

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[28] Similarly, Dr. Sherman stated that her methodology was reliable because she looked at medical records, which contained the results of physical exams performed by other physicians (and medical histories taken by other physicians) A. 5103, at illnesses across the population, and then applied the medical literature to narrow down the cause (A5097, 5099).

[29] Just as a doctor can sometimes reach a reliable differential diagnosis without performing a physical examination, there may also be circumstances in which a doctor conducts a physical examination but this is insufficient to create a reliable differential diagnosis in the absence of the additional data.

else that there is no need to examine alternatives. *See Peteet v. Dow Chemical Co.*, 868 F.2d 1428, 1431-32 (5th Cir.), *cert. denied*, 493 U.S. 935, 110 S. Ct. 328 (1989) (allowing a doctor to testify as to causation based on an examination of medical records, of the plaintiff's deposition, and of the medical literature).[30]

In light of the foregoing discussion, we conclude that where Dr. Sherman or DiGregorio offered an opinion as to the source of a party's illness, the district court abused its discretion in excluding that opinion under Rule 702 unless either (1) Dr. Sherman or DiGregorio engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes *and* the doctor offered no good explanation as to why his or her conclusion remained reliable, or (2) the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and Dr. Sherman or DiGregorio offered no reasonable explanation as to why he or she still believed that the defendants' actions were a substantial factor in bringing about that illness.

In response, of course, the doctor could offer an explanation based on the plaintiffs' medical history, laboratory tests or any other reliable source.[31] *Cf. Cantrell v. GAF*

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[30] We note that it is not only simple cases that could justify a finding of reliability absent employment of a significant number of diagnostic techniques. Imagine a patient who comes to a physician with medical records demonstrating illness A known to be strongly associated with chemical X and evidence of exposure to that chemical. Also, imagine that there are other chemicals, foods, or other substances to which the patient has been exposed which sometimes, though much less frequently, cause this same illness. With a basic understanding of probabilities, a physician might very well be able to reliably conclude that a person exposed to chemical X was more likely than not to have contracted illness A as a result of that exposure than as a result of any other cause.

[31] (Plaintiffs argue that the test for admissibility of Dr. Sherman's testimony should be even lower, because of the "substantial factor" standard of causation for tort law in Pennsylvania. *See*

Corp., 999 F.2d 1007, 1012-13 (6th Cir. 1993) (applying *Daubert* to uphold the admissibility of the testimony of a doctor that asbestos had caused the plaintiffs'

Hamil v. Bashline, 392 A.2d 1280, 1284 (Pa. 1978). Under this standard, a plaintiff "need not exclude every possible explanation of the [injury]; it is enough that reasonable minds are able to conclude that the preponderance of the evidence shows defendant's conduct to have been a substantial cause of the harm to plaintiff." *Id.* at 1285. Thus, plaintiffs assert. Dr. Sherman and Dr. DiGregorio did not have to rule out alternative causes; they merely had to establish that PCBs were a substantial factor in plaintiffs illnesses.

We agree with the plaintiffs that because we are analyzing reliability for the purposes of litigation not for purposes of science, the substantive standard of causation can affect the standard of admissibility. However, we do not think that the "substantial factor" standard lowers the burden of admissibility here. The substantial factor test applies when a number of different factors each contribute to a particular result; "if two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about." Restatement 2d of Torts § 432. Where defendant's actions and other actions each contribute to harm to a plaintiff, for example, when a sick plaintiff dies after medical malpractice by defendant that might have saved her, "defendant is legally liable unless it can be shown that death would have resulted regardless of the action or inaction of defendant." *Hamil*, 392 A.2d at 1286.

Here, however, if plaintiffs' experts failed to rule out alternative causes, it means that these alternative causes may have been the sole causes of plaintiffs' injuries—PCBs may not have played any role at all and certainly may not have been sufficient to bring about the plaintiffs' injuries. Testimony that PCBs increased the risk that plaintiffs would contract the injuries that they contracted does not show that PCBs were a substantial factor in those injuries. Moreover, testimony that plaintiffs' exposure to PCBs makes it likely that PCBs were a substantial factor in plaintiffs' injuries cannot reliably establish that PCBs were in fact a substantial factor unless the expert thought about the possibility that other potential causes of those injuries were in fact the *sole* cause of those injuries. Even under the substantial factor test, plaintiffs must prove that defendants' actions *were* a cause of plaintiffs'

laryngeal cancer based on the unusually high incidence of this cancer among the plant workers despite the fact that the defendants had pointed to smoking as a possible alternative cause of the cancer). Thus, to avoid exclusion of his or her opinion, Dr. Sherman or DiGregorio did not have to conduct every possible test to assess whether his or her view was correct so long as he or she employed sufficient diagnostic techniques to have good grounds for

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injuries before the burden switches to defendant to show that the injuries would have occurred even absent any action by the defendant. *See Arnold v. Loose*, 352 F.2d 959 (3d Cir. 1965) (Pennsylvania law precludes an expert from testifying based on guess or conjecture, thus, the district court properly excluded a doctor's opinion that an individual lapsed into a diabetic coma before an accident when the doctor failed to rule out the alternative possibility that the brain injury suffered during the accident caused the coma).

The plaintiffs do cite several cases that hold that where plaintiffs present expert testimony that "defendant's conduct did, with a reasonable degree of medical certainty, increase the risk that the harm sustained by plaintiff would occur," it creates a triable issue of fact for the jury as to whether defendant's actions were a substantial factor." *Hamil*, 392 A.2d at 1289. But, even if this is a substantive rule of law rather than a procedural rule and thus applies in federal court, almost all of the cases articulating this rule are medical malpractice cases in which it is clear that defendant's actions were *a* contributing factor to plaintiff's injuries; moreover, these cases specifically rely on Restatement Second of Torts § 323(a), on the negligent performance of undertaking to render services, which they hold "relax[es] the degree of certitude normally required of plaintiff's evidence in order to make a case for the jury." *Id.* at 1286; *see also Gradel v. Inouye*, 421 A.2d 674, 677 (Pa. 1980) (squib), *Jones v. Montefiore Hospital*, 431 A.2d 920, 923 923 (Pa. 1981) (squib). Plaintiffs only cite one case outside the context of § 323(a) and it is a Pennsylvania Superior Court case which does not explain why it is applying *Harnil* as it does. *See Pirches v. General Accident Ins. Co.*, 511 A.2d 1349, 1351-52 (Pa. Super. 1986). We do not think that this latter case articulates the law in Pennsylvania, and we thus think that Pennsylvania substantive law does not change the federal standard for the admissibility of expert testimony.

his or her conclusion that the plaintiff's illness was caused by PCBs.

The conclusion that the opinion of a doctor who has engaged in few standard diagnostic techniques should be excluded unless the doctor offers a good justification for his or her conclusion is supported by the case law. *Cf. In re Agent Orange Product Liability Litigation*, 611 F.Supp. 1223, 1234-38, 1246-47 (E.D.N.Y. 1985) (excluding testimony by a doctor, based on his evaluation of form statements signed by the plaintiffs in which they indicated that they had been exposed to Agent Orange and then checked off their symptoms, that Agent Orange had caused plaintiffs' injuries at least absent evidence of an alternative cause); *Arnold v. Loose*, 352 F.2d 959 (3d Cir. 1965) (holding that Pennsylvania law precludes an expert from testifying based on guess or conjecture, and thus that the district court had properly excluded a doctor's opinion that an individual had lapsed into a diabetic coma before an accident when the doctor had failed to rule out the alternative possibility that the brain injury suffered during the accident had caused the coma); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420 (5th Cir. 1987) (excluding doctor's testimony that the defendant had caused plaintiff's illness, because the doctor had relied on a medical history that omitted important information, the doctor had admitted the ailments could have a number of causes, and there was no good evidence that the defendant had caused these types of illnesses).[32]

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[32] The *Viterbo* court concluded:

> We do not hold, of course, that admissibility of an expert opinion depends upon the expert disproving or discrediting every possible cause other than the one espoused by him. Here, however, Dr. Johnson has admitted that Viterbo's symptoms could have numerous causes and, without support save Viterbo's oral history, simply picks the cause that is most advantageous to Viterbo's claim. Indeed, Dr. Johnson's testimony is no more than Viterbo's testimony dressed up and sanctified as the opinion of an expert. Without more than credentials and a sub-

We acknowledge that some of these cases can be read to indicate that an expert's opinion on causation should *always* be excluded absent employment of standard diagnostic techniques to rule out alternative causes. *See also Carroll v. Litton Systems, Inc.*, 1990 U.S. Dist. LEXIS 16833, *49, 53, 55 (W.D.N.C. 1990) (excluding testimony of medical doctors where they failed to employ differential diagnosis and rule out alternative causes). However, for the reasons explained above, we think that there will be some cases in which a physician can offer a reliable differential diagnosis without examining the patient, looking at medical records, taking a medical history, and performing laboratory tests.

We also think that the view of defendants' experts that a physical examination and review of medical records are integral parts of differential diagnosis is not based solely on their claim that these diagnostic techniques are necessary to assess causation but also on a view that these techniques are necessary to determine what illness a patient has contracted in the first place. In *In re "Agent Orange"*, 611 F.Supp. at 1246 (E.D.N.Y. 1985), Judge Weinstein faced a similar situation. In the end, he excluded a doctor's testimony as to causation, where the evidence of the patient's illnesses stemmed solely from a checklist they had filled out. He explained, "here we have statements of problems ranging from baldness to the most serious cancers . . . . While courts allow reliance on patient statements, they are based upon a personal history corroborated by medical records, a physical examination and medical tests." *Id.* He added, "[h]ere, the usual inducement to candor with a physician—the hope of successful treatment or diagnosis—was wholly lacking. *Cf.* Fed. R. Evid. 803(4). Instead, plaintiffs had every in-

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jective opinion, an expert's testimony that 'it is so' is not admissible."

Id. at 424.

centive to be overinclusive in describing their symptoms . . . ." *Id.*

Judge Weinstein was correct. We do not doubt the propriety of a medical report prepared just for litigation purposes, but a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply in order to determine that a patient is ill and what illness the patient has contracted. Thus, we are satisfied that where Drs. DiGregorio or Sherman based their conclusion as to a plaintiff's symptoms solely on the plaintiff's self-report of illness in preparation for litigation, the district court acted within its discretion in excluding the testimony as based on an unreliable source of information.

On the other hand, we think that evaluation of the patient's medical records, like performance of a physical examination, is a reliable method of concluding that a patient is ill even in the absence of a physical examination. It is hornbook law that medical records are admissible for such a purpose—"[a]s to hearsay *symptoms told by third persons*, . . ., where the information is that of an *attending nurse* or *physician* having personal observation and an interest in learning and describing accurately, there seems to be every reason for admitting testimony based in part on this." 3 John Henry Wigmore, *Wigmore on Evidence* § 688(4) (Chadbourn ed. 1970). *See also Cohen v. Albert Einstein Medical Ctr.*, 592 A.2d 720 (Pa. Super. 1991) (holding that the testimony of a doctor who relied on medical records without conducting a physical exam was admissible proof that the plaintiff suffered from a psychiatric disorder); *Peteet v. Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir. 1989) (allowing testimony of a doctor who had not physically examined the plaintiff and noting that, "[a] personal examination of the person or object of the expert's testimony is not required under Fed. R. Evid. 703"). Hence, we think that generally, a

doctor only needs one reliable source of information showing that the plaintiff is ill and either a physical examination or medical records will suffice—but the doctor does need at least one of these sources.

Moreover, as we explained above, in order to establish causation sufficiently reliable for us to overturn the district court's decision as an abuse of discretion, where Drs. Sherman or DiGregorio engaged in few of the standard procedures of differential diagnosis, they had to offer a good explanation as to why their conclusion remained reliable. Where they did employ such standard techniques, they still had to offer such an explanation if the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions.

We now apply these principles to the opinions of Drs. DiGregorio and Sherman regarding particular plaintiffs.

a. The opinion of Dr. DiGregorio

As we have noted, Dr. DiGregorio did not examine the plaintiffs or review their medical records; he simply relied on their answers to a questionnaire he gave them. Under the rule we have articulated above, *see supra* pp. 82-83. Dr. DiGregorio could not even reliably conclude that the plaintiffs had any illness. In fact, Dr. DiGregorio admitted that without examining the plaintiffs he could not state to a reasonable degree of medical certainty that they had been injured as a result of exposure to PCBs. We now uphold the district court's decision to exclude his testimony as within that court's discretion. Dr. DiGregorio simply lacked the foundation to make the judgments he did. For that reason alone, the district court was correct to grant summary judgment against the Hanes plaintiffs on their personal injury claims.

Moreover, inasmuch as he did not engage in standard diagnostic techniques, we presume that Dr. DiGregorio's

conclusions as to causation were unreliable unless he offered good grounds for concluding that they were correct. *See supra* pp. 79-80. But Dr. DiGregorio stated that his preliminary assumption was that *all* of the plaintiffs' injuries that they checked off in the questionnaire were caused by PCBs, and he did not explain what justified this assumption. For example, Dr. DiGregorio testified that PCBs caused Cathlene Brown's bruising but admitted that the birth control pills she took could also have caused the bruising. He explained that in order to confirm his diagnosis he would have to "investigate with her when did she start the bruising, how long has she been bruising, does she have any bruising now, and how long has she been on the contraceptives," but noted that his diagnosis would remain unchanged until he could conduct this investigation. Dr. DiGregorio nonetheless provided no reason to explain why he thought that PCBs were more likely to have caused Brown's bruising than contraceptives.[33]

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[33] Dr. DiGregorio's differential diagnoses of the other Hanes plaintiffs suffer from the same problem. He testified that PCBs had caused Christopher Brown to have an abnormal liver function test which he suggested was a sign that something was wrong with the liver. JA 6579. But he admitted that viruses, alcohol and drugs all could cause an abnormal liver function test and that he had not yet conducted the analysis necessary to rule out these possibilities. He stated that, as his working diagnosis, he believed PCBs were the cause because, "[h]e has an elevated PCB level and he has an abnormal liver condition. And as far as I'm concerned that's the number one differential." JA 2991. Yet Dr. DiGregorio did not indicate why he thought PCBs were the "number one differential."

With respect to Craig Brown's elevated L.D.H. enzyme test. Dr. DiGregorio was asked whether it would affect his opinion that PCBs had caused this elevation if he were told that Brown's medical records indicated that he drank a few cans of beer every work night and two to three six packs on Thursday, Friday, and Saturday nights. JA 2843-45. He replied that it would not unless he looked at the charts showing the effect of alcohol on the liver by quantity of alcohol and size and age of the person. JA 2845. But again Dr. DiGregorio offered no explanation as to why he con-

His analysis of other Hanes plaintiffs was similarly flawed, as explained in the margin.

Presumably, Dr. DiGregorio's general reasoning was that all of the plaintiffs had significant exposure to PCBs, that PCBs are a known cause of the illnesses of the various plaintiffs, and that, in the absence of any indication that any plaintiff had been exposed to something more likely to cause his or her illness than PCBs, it was reasonable to conclude that PCBs were a likely cause. But Dr. DiGregorio did not point to any evidence showing that PCB exposure was so likely to produce the type of illnesses the plaintiffs had in comparison to other possible causes to which plaintiffs had likely been exposed that it was reliable to conclude that PCBs were the cause without further analysis. We think that the district court essentially, and properly, read Dr. DiGregorio's testimony as showing that his opinion that PCBs caused plaintiffs' illnesses was only a hypothesis which he had yet to attempt to verify or disprove by subjecting it to the rigors of scientific testing. Thus, the district court properly excluded Dr. DiGregorio's testimony with respect to the Hanes plaintiffs'

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tinued to stick to his opinion. Dr. DiGregorio also opined that Mary Retta Johnson was anemic, as indicated by her blood test results, and that this anemia was caused by PCB exposure. He maintained this conclusion despite admitting that there were many other potential causes for anemia including bleeding, cancer, and a decrease of bone marrow function and stating that all would have to be investigated. JA 2966.

Finally, Dr. DiGregorio asserted that Curtis Brown's insomnia and elevated triglycerides were caused by PCB exposure. He conceded that there were many possible causes of insomnia and elevated triglycerides (he said the major cause of the latter was diet) but stated that he had to base his diagnosis on the information he had available at the time. JA 2880-81, 2895-97. He did not gather any information on these alternative possibilities; he did not even ask about Curtis Brown's diet. JA 2895-97. The other Hanes plaintiffs do not claim any present physical injuries as a result of PCB exposure.

personal injury claims and correctly granted summary judgment against them on these claims.

b. The opinion of Dr. Sherman

Unlike Dr. DiGregorio, Dr. Sherman reviewed the medical records of all of the plaintiffs on whose behalf she testified (the Kohn/Klehr plaintiffs). Moreover, she physically examined two plaintiffs (and took their medical history). Thus, she had a reliable source of information that each of the plaintiffs were actually ill. Dr. Sherman also had information on the history of PCBs in the Paoli area, the level of PCBs in plaintiffs' soil, some evidence of the level in their blood (for many plaintiffs), and the medical histories of the plaintiffs that were contained in their medical records. Nonetheless, with respect to those plaintiffs whom Dr. Sherman did not examine, she had little, if any data with which to rule out alternative causes of their illnesses. She did not take medical histories herself, there is no evidence in the record showing the extent to which medical histories were present in the plaintiffs' medical records, and she performed no reliable laboratory tests.

The district court excluded Dr. Sherman's testimony as a whole, on the grounds that her testimony demonstrated that she *never* considered alternative causes and *always* found PCBs to be the cause. If the district court was correct, then we would likely uphold its exclusion even if the defendants did not point to specific alternative causes that Dr. Sherman failed to consider for those plaintiffs whom she did examine. Given the number of plaintiffs in this case, we think that if there were no evidence that Dr. Sherman ever considered alternative causes, it would be reasonable for the district court to have presumed that she did not consider alternative causes even for those plaintiffs whom she examined and for whom she had significant data about alternative possibilities.

However, as we read Dr. Sherman's testimony, when she said that she did not rule out other causes, that does

not necessarily mean that she failed to consider them, but rather only that she did not rule them out as a possible cause or a partial cause in combination with PCBs, which she concluded were *one* significant factor in plaintiffs' illnesses. More particularly, where defendants point to evidence that Dr. Sherman acknowledged failing to rule out alternative causes, Dr. Sherman was merely admitting that there might have been other causes while stating that PCBs were a significant cause.

Plaintiffs point to several instances in which Dr. Sherman specifically considered alternative causes. She specifically considered Charles Stanbach's smoking as a possible cause of his esophageal cancer before ruling it out based on when he had stopped smoking and the types of changes he had in his cells. Moreover, *she declined* to say with a reasonable degree of medical certainty that the redness around George Burrell's eyes had been caused by PCB exposure even though PCBs were associated with such redness in the literature—she explained that she could not rule out alternative causes. For similar reasons she refused to say that Priscilla Burrell's headaches were caused by PCBs, and she opined that Monica Hilton's skin reaction was caused by poison ivy rather than exposure to PCBs. Dr. Sherman further testified that she could not state with a reasonable degree of medical certainty that PCBs caused ringing in the ears even though three of the plaintiffs complained of such ringing.

In view of these facts, we will not uphold the district court's *blanket* exclusion of Dr. Sherman's testimony without examining her testimony concerning particular plaintiffs. Applying the *Daubert* analysis we conducted above. *see supra* at p. 78, unless Dr. Sherman presented a good explanation for why she could reasonably testify that the illnesses of the plaintiffs whom she did not examine were caused by PCBs, the district court was within its discretion in excluding Dr. Sherman's testimony. With respect to those plaintiffs whom Dr. Sherman did examine, we conclude that she employed a sufficient number of standard

diagnostic techniques that the district court should have presumed that her testimony was reliable. Thus, Dr. Sherman's testimony is admissible with respect to these plaintiffs unless the defendants pointed to particular potential alternative causes and she was unable to explain why she thought these alternatives had not caused the plaintiffs' illnesses. *See supra* at pp. 76-77. In analyzing the adequacy of Dr. Sherman's explanations, we will weigh in the balance Dr. Sherman's somewhat dubious expertise—a factor we have deemed important under the Supreme Court's flexible *Daubert* inquiry. *See supra* at 43-44.

Defendants also contend that even if Dr. Sherman's testimony is admissible, it is insufficient to allow plaintiffs to survive summary judgment. Because plaintiffs did not rule out alternative causes, defendants submit, her testimony cannot establish that defendants' PCBs more likely than not caused plaintiffs' injuries. We disagree, for assuming that Dr. Sherman's testimony is admissible, her assertion that PCBs caused plaintiffs' medical injuries is sufficient to establish a genuine issue of material fact on causation. However, for reasons we have explained *supra* pp. 59-60, defendants are correct that under Pennsylvania law they are entitled to summary judgment where Dr. Sherman refused to state her conclusions with a reasonable degree of medical certainty or its substantive equivalent, and for reasons we will explain *infra*, they are entitled to summary judgment where the illness to which Dr. Sherman attested was asymptomatic. *See infra* p. 128 & n. 51 (concluding as part of an analysis of Pennsylvania's law on medical monitoring, that Pennsylvania does not recognize a cause of action for physical changes which are asymptomatic). Thus, in analyzing Dr. Sherman's testimony with respect to the particular plaintiffs, we will affirm the district court's grant of summary judgment with respect to some of the plaintiffs' claims without reaching the issue of the reliability of Dr. Sherman's methodology.

i. Bessie Cunningham

Dr. Sherman examined Bessie Cunningham, took her medical history and reviewed her medical records. Sherman testified that PCBs significantly contributed to Cunningham's headaches, sinusitis, blurred vision, arthritis, hypertension, peripheral swelling (edema) and nerve damage, and hysterectomy following three pregnancy losses. However, defendants offer a number of reasons why Dr. Sherman's testimony is not admissible and we turn to these contentions now.

First, Dr. Sherman's view that PCBs cause headaches partly relied on studies of the Yusho victims, studies which the district court properly excluded under Rule 403. *See infra* p. 123. But the fact that these studies would be inadmissible as substantive evidence before a jury does not render them unreliable as a source of data for experts who are in better position to evaluate (and discount them), and we have not deemed them to be unreliable as a source of such data. *See infra* p. 123. Thus, we do not think that Dr. Sherman's reliance on this data renders her entire methodology as to the source of Bessie Cunningham's headaches unreliable. Nor did the defendants point to an alternative source of these headaches that Dr. Sherman failed to consider. Thus, defendants did not put forth a basis for excluding Dr. Sherman's testimony regarding these headaches.

Dr. Sherman also testified that PCBs caused Bessie Cunningham's arthritis/arthralgia. She stated that Cunningham probably had both arthritis and arthralgia and that, of the types of arthritis, Bessie Cunningham probably had osteoarthritis. Defendants submit that Dr. Sherman's testimony is fatally inconsistent insofar as she opined that the only known cause of osteoarthritis is wear and tear. But defendants did not ask Dr. Sherman why she concluded that PCBs caused Mrs. Cunningham's arthritis if the only known cause of osteoarthritis is wear and tear; nor did they ask her how she eliminated wear

and tear as a likely cause. They also did not ask about possible alternative causes of arthralgia. Thus, they did not establish a basis for excluding Dr. Sherman's testimony that PCBs caused Bessie Cunningham's arthritis/arthralgia.

Dr. Sherman also opined that PCBs caused Cunningham's hypertension by elevating her lipid levels or through some other mechanism. Although she acknowledged that tests did not show elevated lipid levels. she stated that the tests were not necessarily an accurate indicator because lipid levels change rapidly and added that the PCBs might have caused the hypertension through a mechanism other than raised lipid levels. In any case, we have no reason to believe that, for differential diagnosis to be a reliable methodology, all of the data a doctor acquires must point to the same conclusion. The lipid tests were unreliable at all events, *see supra* p. 68, and thus we do not think that the fact that the lipid tests failed to support Dr. Sherman's conclusions inherently renders those conclusions unreliable. Finally, defendants did not point to any alternative causes of Cunningham's hypertension that Dr. Sherman failed to rule out. Thus, we think that her testimony that PCBs caused Bessie Cunningham's hypertension should not have been excluded.

Although Dr. Sherman initially testified that PCBs contributed to Mrs. Cunningham's pregnancy losses and caused her to have a hysterectomy, she later opined that PCBs were only a possible cause. She admitted she did not know the circumstances of Mrs. Cunningham's hysterectomy; nor did she know when Mrs. Cunningham's miscarriages had occurred in relationship to the time that PCBs began to be used at Paoli. Thus, when defendants pointed to possible alternative causes, Dr. Sherman could provide no justification for her elimination of these alternative causes thus rendering her testimony inadmissible. Even if her testimony were admissible, Dr. Sherman's statement that PCB's were a possible cause did not have sufficient scientific certainty to survive summary judgment. *See Schulz*, 942 F.2d at 208, *supra* p. 58.

Dr. Sherman's entire testimony explaining her conclusion that PCBs caused Mrs. Cunningham's sinusitis was as follows:

> I said that I thought that the chronic exposure to PCBs, dibenzofurans, dioxins and the associated chemicals from the Paoli yard interfered with her immune function, and secondarily, she had long time multiple complaints with respiratory upper respiratory problems. I think it's a fact. I don't think it's the sole cause.

This testimony seems to place heavy reliance on the unreliable immunological data, *see supra* p. 68, and therefore we hold that the district court acted within its discretion in concluding that Dr. Sherman's entire methodology with respect to Bessie Cunningham's sinusitis was unreliable and thus inadmissible.

In sum, we conclude that while the district court properly excluded Dr. Sherman's testimony with respect to Bessie Cunningham's pregnancy losses, hysterectomy, and sinusitis, the court abused its discretion in excluding Dr. Sherman's testimony that PCBs caused Cunningham's headaches, arthritis/arthralgia and hypertension.

ii. Amber Burrell

Dr. Sherman examined Amber Burrell, took a medical history of her from Amber's mother, and reviewed Amber's medical records, Dr. Sherman concluded that Amber's skin reactions were prodromes of chloracne caused by exposure to PCBs, and that Amber's recurring respiratory ailments and infections, immune system damage, and absence of appropriate ankle reflexes were also caused by exposure to PCBs.

The defendants' experts pointed to a possible alternative cause of Amber's respiratory ailments and infection, suggesting that these ailments might have been normal childhood problems. But Dr. Sherman testified that, although

she did not know whether Amber had contracted more respiratory infections than most children, the unusual nature of Amber's skin abnormalities and premature breast development combined with Amber's elevated leukocyte counts shown in hospital records and current immunological tests and with the fact that Amber's infections largely went away when she moved away from Paoli, demonstrated that PCBs had caused Amber's respiratory ailments and infections.

Hence, when asked about a possible alternative cause, Dr. Sherman pointed to a variety of data as justification for her conclusion that PCBs had caused Amber's respiratory infections. Regardless of whether Dr. Sherman's conclusion was correct, her methodology was reasonably reliable. Although part of Dr. Sherman's differential diagnosis relied on current immunological tests that the district court excluded as unreliable, this was only a small part of the basis for her opinion. Thus, the district court abused its discretion in excluding Dr. Sherman's testimony regarding Amber's respiratory ailments.

Dr. Sherman also testified that PCBs caused Amber's skin abnormalities which she asserted were prodromes of chloracne. She stated that the only reason Amber did not develop full blown chloracne was that she moved away from Paoli. But the defendants showed that Amber's skin condition might have been normal teenage acne with no relationship to PCBs. Dr. Sherman offered no explanation as to why she eliminated this possibility—at least no explanation reliable enough to be helpful to the jury. Dr. Sherman admitted she was not an expert in dermatology, and she demonstrated little knowledge about chloracne. She incorrectly testified that "we don't know whether ordinary teenage acne isn't really chloracne." *See supra* p. 63. Moreover, she acknowledged that she was not sure if she had ever seen acne on anyone who had not been exposed to PCBs, and opined that the only way to determine whether a patient's acne was caused by PCBs was to do a history of their exposure to PCBs (presumably,

if the patient had been exposed to PCBs then ipso facto his or her acne was caused by PCBs). This suggests that Dr. Sherman made no effort to employ differential diagnosis to eliminate possible alternative causes of Amber's skin abnormalities; we therefore uphold the district court's determination that Dr. Sherman's testimony on Amber's skin condition was inadmissible.[34]

Dr. Sherman also testified that PCBs were a significant factor in Amber's reduced ankle reflexes. However, she was not willing to answer yes or no to the question whether she could say this with a reasonable degree of medical certainty. Thus, the district court properly granted summary judgment on this claim regardless of whether Dr. Sherman's testimony was admissible. *See supra* pp. 62-63.

In sum, the district court properly excluded Dr. Sherman's testimony regarding Amber Burrell's skin condition and granted summary judgment on her claim regarding ankle reflexes, but abused its discretion in excluding her testimony regarding Amber's respiratory ailments.

iii. Priscilla Burrell

Dr. Sherman did not examine any plaintiffs other than Bessie Cunningham or Amber Burrell, nor did she take their medical histories. The district court properly excluded Dr. Sherman's testimony with respect to all of these plaintiffs because she did not advance a reliable explanation as to why she ruled out alternative causes with respect to any of them. We will delineate Dr. Sherman's failure to offer such an explanation beginning with her testimony regarding Priscilla Burrell.

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[34] Dr. Sherman also testified that Amber's treating physician thought that PCBs "could be a factor . . . in this child's skin reaction and her illness." (JA 868). But this tentative opinion, even if it constituted data reasonably relied upon by an expert, was not rendered with a sufficient degree of assurance for Amber to avoid summary judgment on this claim.

Dr. Sherman did not examine Priscilla Burrell, nor did she take her medical history. She did talk to Priscilla Burrell and reviewed her medical records formulated by doctors who had examined her. Based on these medical records, Dr. Sherman testified that Priscilla Burrell suffered skin problems, two pregnancy losses, dizziness, ringing in her ears, and kidney damage, all as a result of her exposure to PCBs. Subsequent to Dr. Sherman's deposition and entry of a district court order that she should not supplement her expert report, the thirty-three year old Mrs. Burrell was diagnosed as having kidney cancer.

Dr. Sherman's assessment of the cause of Priscilla Burrell's skin problems suffers from the same methodological flaws as her opinion with respect to Amber's skin problems. Similarly, in linking PCBs to Priscilla Burrell's pregnancy losses, Dr. Sherman failed even to ascertain whether these losses had been due to optional abortions. With respect to dizziness, Dr. Sherman testified that infections cause dizziness and that she was unable to state whether they had done so here. Dr. Sherman took no steps that might have allowed her to conclude that PCBs rather than infections caused Mrs. Burrell's dizziness. Thus, she did not offer any explanation as to why she had eliminated even the most obvious possible alternative causes of skin problems, pregnancy losses or dizziness.

Dr. Sherman also testified that PCBs caused kidney damage which resulted in the blood in Mrs. Burrell's urine. But the only basis for Dr. Sherman's belief that there even was blood in Mrs. Burrell's urine was a conversation with Martin D'Urso, plaintiffs' counsel. Dr. Sherman did not examine Mrs. Burrell's medical records with respect to this problem and thus, did not have a reliable basis for concluding that Burrell had kidney problems much less that those problems were caused by PCBs. Dr. Sherman offered no explanation as to what alternative causes she considered for Mrs. Burrell's kidney problems or how she ruled them out. Thus, Dr. Sherman's testimony regarding

Priscilla Burrell's injuries was unreliable and hence inadmissible.

Plaintiffs made no effort to ask the district court to allow Dr. Sherman to supplement her opinion in light of the new diagnosis of kidney cancer, nor did they offer the opinion of Mrs. Burrell's treating physician in opposition to summary judgment. Because plaintiffs presented no admissible evidence on Priscilla Burrell's personal injury claims, the district court properly granted summary judgment for the defendants on these claims.

iv. Monica Hilton

Dr. Sherman did not examine Monica Hilton. She opined that PCBs contributed to Monica Hilton's susceptibility to cough and respiratory problems and to her (related) augmented immune response. But Dr. Sherman failed to explain why she thought that PCBs were a cause of these problems in light of possible alternative causes. Thus, the district court properly excluded Dr. Sherman's testimony with respect to Monica Hilton and granted summary judgment against her on her personal injury claims.

v. Matthew Cunningham

Dr. Sherman did not examine Matthew Cunningham but nonetheless testified that PCBs caused his heart disease including hypertension, aortic sclerosis, myocardial infarction and ultimately his death. She also averred that PCBs caused Cunningham's liver damage.

Dr. Sherman theorized that PCBs caused Mr. Cunningham's heart disease either by elevating his cholesterol and triglyceride fractions or by directly affecting his tissues. While she later admitted that she was not sure whether these two mechanisms were distinct and that there were no tests showing an elevation of cholesterol levels, she pointed out that there was a test showing elevated triglyceride levels. But the district court properly excluded this test as unreliable. *See supra* pp. 67-68. Absent reli-

ance on this data, Dr. Sherman expressed no reason for her conclusion that PCBs caused Cunningham's heart disease nor why she had ruled out the possibility of alternative causes for this disease. Thus, the district court acted within its discretion in excluding her opinion.

While Dr. Sherman admitted that hereditary factors may have increased Mr. Cunningham's risk of contracting hypertension, she did not withdraw her opinion that PCBs were a significant factor in his developing hypertension and other forms of heart disease. But once again she failed to explain why she thought that PCBs rather than alternative causes were responsible and thus the district court properly excluded her testimony.

Dr. Sherman also asserted that PCBs caused Mr. Cunningham's cellular liver damage, but there was no evidence indicating that that damage had any symptoms. Thus, the district court properly granted summary judgment on the claim of liver damage because the damage was asymptomatic, *see infra* p. 128 & n. 51, and on the claims of hypertension and heart disease because Dr. Sherman's causation opinion with respect to these diseases was inadmissible.

vi. Patricia Ingram

Dr. Sherman did not examine Patricia Ingram but did review her medical records. She testified that PCBs were a significant factor in Patricia Ingram's chronic obstructive pulmonary disease and asthma, and her increased cellularity. She added that the steroids that Patricia Ingram took for her asthma caused her diabetes and therefore that PCBs indirectly caused that diabetes. But she could not testify with a reasonable degree of medical certainty as to the particular mechanism by which PCBs caused the asthma and ultimately the diabetes.

Dr. Sherman conceded that she had not ruled out possible alternative causes of Patricia Ingram's asthma,

although this may have just meant that she had not *completely* eliminated that these alternatives as causal agents. Yet this testimony, when considered in the light of Dr. Sherman's limited expertise about asthma show that her methodology in evaluating the causation of Patricia Ingram's asthma was unreliable. This renders her methodology in relating PCBs to diabetes unreliable as well because her methodology depended on the fact that PCBs had caused Ingram's asthma. Moreover, Dr. Sherman acknowledged that she did not consider any possible causes of Patricia Ingram's diabetes other than her asthma treatment. As for increased cellularity, there is no indication that there are any symptoms associated with this condition and thus it cannot be the basis of a personal injury claim. *She infra* p. 128 & n. 51. Because Dr. Sherman's testimony on the cause of Patricia Ingram's illnesses is inadmisisble and because increased cellularity is asymptomatic, Patricia Ingram's personal injury claims cannot survive summary judgment.

vii. John Ingram, Sr.

Dr. Sherman did not examine John Ingram, Sr. but testified that PCBs caused his elevated triglycerides, augmented immune response and hypertension. The first two are asymptomatic and non-compensable. *See infra* at 128 & n. 51. As for hypertension, Dr. Sherman indicated that because she was working solely from medical records, she had not examined possible alternative causes. Therefore, Dr. Sherman's testimony on John Ingram, Sr.'s hypertension must be excluded as unreliable which means that John Ingram, Sr.'s personal injury claims cannot survive summary judgment.

viii. John Ingram, Jr.

Dr. Sherman reviewed John Ingram, Jr.'s medical records but did not examine him. She testified that PCBs caused a suppression of his immune system which signifi-

cantly contributed to his recurring respiratory infections. However, the only evidence Dr. Sherman cited for the proposition that John Ingram, Jr.'s immune system was in fact suppressed was the AAL immunological test results which are unreliable and inadmissible. *See supra* p. 68. Thus, Dr. Sherman's methodology for concluding that John Ingram, Jr.'s personal injuries were caused by PCBs is unreliable. As a result, her opinion is inadmissible and Ingram's personal injury claims cannot survive summary judgment.

ix. George Burrell

Dr. Sherman stated that George Burrell's headaches, dizziness, ringing in the ears, and eye irritations were compatible with the pattern of illnesses caused by PCBs but she did not state with a reasonable degree of medical certainty that PCBs caused Mr. Burrell's medical problems. Without sufficient evidence of causation, these claims cannot survive summary judgment.

x. Wallace Cummins

Dr. Sherman did not examine Wallace Cummins, nor did she read his medical records before submitting her expert report. By the time of the *in limine* hearing, however, Dr. Sherman had read Cummins' medical records and she listed Cummins' cancer as evidence for the proposition that Paoli residents had a higher incidence of kidney cancer than was present in the general population. However, she did not testify that PCBs caused Cummins' cancer. Therefore, her testimony, even if it were admissible, is insufficient to enable Cummins to survive summary judgment.

Plaintiffs represent that Cummins' treating physician, Dr. Stanley Glauser, will testify that PCBs caused Cummins' kidney cancer and his hypertension. However, while Cummins listed Dr. Glauser as a fact witness for trial, he did not submit his affidavit in opposition to summary

judgment. Indeed, the only reference to Dr. Glauser in the summary judgment record is an unsupported reference in plaintiffs' opposition brief to the deposition of Cummins' wife, who testified as to what another physician had told her that Dr. Glauser had told him about Cummins' condition. Such hearsay testimony is insufficient to survive a motion for summary judgment. Fed. R. Civ. P. 56(e). *See Fowle v. C & C Cola, Div. of ITT-Continental Baking Co.*, 868 F.2d 59, 67 (3d Cir. 1989); *Garside v. Osco Prag*, 895 F.2d 46, 50 (1st Cir. 1990).[35] Thus, Cummins' personal injury claims cannot survive summary judgment.

xi. April Ingram

Dr. Sherman testified that April Ingram had skin problems, but she did not testify that PCBs caused these problems. She did allege that PCBs caused April's immunological abnormalities but these are asymptomatic. *See infra* at 128 & n. 51. Thus, April Ingram's personal injury claims cannot survive summary judgment.

xii. The Remaining Plaintiffs

Dr. Sherman did not testify that PCBs caused illnesses of any of the other plaintiffs, including those seeking damages for personal injuries. For their personal injury claims, these plaintiffs relied on the testimony of the experts whose testimony the district court excluded for

[35] Because Dr. Glauser has become ill, plaintiffs have asked us for permission to substitute the testimony of Dr. Stephen C. Fox, another of Cummins' treating physicians. However, in order for plaintiffs to be allowed to substitute Dr. Fox for Dr. Glauser and to rely on his testimony to survive summary judgment, Dr. Glauser's opinion must have enabled plaintiffs to survive summary judgment in the first place. Otherwise, the plaintiffs would be adding new evidence on appeal in order to survive summary judgment. For the reasons explained in the text, we do not think that Dr. Glauser's opinion would have enabled plaintiffs to survive summary judgment and thus Dr. Fox's opinion is immaterial.

failure to comply with the court's pre-trial orders. But because the plaintiffs did not point to the testimony of these experts in their opposition to summary judgment, the testimony of these experts does not enable these plaintiffs to survive summary judgment. *See supra* pp. 37-38.

c. *Rule 403*

The district court also excluded Dr. Sherman's testimony under Rule 403, reasoning that the jury would give more probative weight to Dr. Sherman's testimony than it was entitled to, because Dr. Sherman simply attributed all illnesses to PCBs and was evasive on cross examination. This is not an appropriate Rule 403 rationale. We fail to see what characteristics of Dr. Sherman's testimony would make it the subject of the type of 403 balance necessary for its exclusion, such as that it is harder for the jury to evaluate this testimony than any other scientific testimony. *See Downing*, 753 F.2d at 1240. The 403 ruling will be reversed.

d. Summary (DiGregorio and Sherman)

In sum, we will uphold the district court's exclusion of Dr. DiGregorio's testimony regarding causation of the Hanes plaintiffs' personal injuries as based on an unreliable methodology—he failed to examine the plaintiffs, review their medical records, or consider alternative causes of their illnesses. As a result we will affirm the district court's grant of summary judgment against the Hanes plaintiffs on these claims.

Similarly, we will uphold the district court's exclusion of Dr. Sherman's testimony regarding causation of the Kohn/Klehr plaintiffs' present injuries with the exception of the claims of Bessie Cunningham and Amber Burrell. With respect to most plaintiffs, the district court acted within its discretion in concluding that Dr. Sherman's methodology was unreliable. She failed to examine plain-

tiffs or take their medical histories and offered no good explanation as to why she concluded that PCBs were the cause of plaintiffs' illnesses. While we will reverse the district court's ruling that Dr. Sherman is not a qualified expert, we will uphold the court's decision that the immunological tests on the plaintiffs were not of the type reasonably relied on by experts.

However, we have concluded that the district court abused its discretion in excluding Dr. Sherman's testimony regarding some of the present illnesses of Bessie Cunningham and Amber Burrell—both of whom Dr. Sherman did examine and whose medical histories she took, and with respect to whom she performed an acceptable differential diagnosis. Their claims will survive summary judgment so long as the plaintiffs have presented sufficient admissible evidence of their exposure to PCBs and the harm caused by PCBs. We turn to those questions now.

VII. EXPOSURE—THE OPINION OF IAN C.T. NISBET, Ph.D.

The defendants submit that the plaintiffs' personal injury and medical monitoring claims cannot survive summary judgment because they cannot demonstrate that they were exposed to PCBs at levels above the background levels to which members of the general population are exposed.[36] Six plaintiffs (Bessie Cunningham, Matthew

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[36] We note that even if defendants are correct that plaintiffs can only demonstrate exposure at levels within background, this would not necessarily justify the grant of summary judgment for defendants. For example, if everyone in the population had been exposed to substantial amounts of defendants' PCBs such that each individual had high PCB levels, each individual would have PCB livels within the background but this would not justify a verdict for defendants. Normally, plaintiffs could not make out a viable claim if their exposure is within background levels because there would be no reason to believe that their exposure was from the defendants' PCBs as opposed to other PCBs. However, to the ex-

Cunningham, Amber Burrell, Priscilla Burrell, and Patricia Ingram), including the two who have potentially viable personal injury claims, relied on Dr. Ian C.T. Nisbet to demonstrate the "extent of their exposure to PCBs."[37] Dr. Nisbet has a Ph.D. in physics with a specialization in fluid mechanics. Although he has no formal education in toxicology, he has worked exclusively in the field of environmental sciences since 1968, and he has developed and worked on methods for assessing the way chemicals move in the environment and the risks they pose. In 1975, the EPA commissioned Dr. Nisbet to summarize and analyze studies on PCBs. The Electrical Power Research Institute has also commissioned Dr. Nisbet's organization to review PCB literature; indeed, two of the defendants' experts, Drs. Whysner and Chase, were subcontractors on the study. In 1991, the Agency for Toxic Substances and Disease Registry selected Dr. Nisbet as one of three peer reviewers for a toxicological profile on PCBs. Dr. Nisbet has also been involved in six or seven litigated cases involving PCBs—half for plaintiffs, half for defendants. Thus, Dr. Nisbet is a well qualified expert.

Dr. Nisbet began his assessment of plaintiffs' exposure to PCBs by evaluating the history of PCBs at Paoli. He reviewed the plaintiffs' medical records and employment records and the use of PCBs at the Yard, including the increasing concern at the Yard about the potential harm of PCBs and the safety measures taken as a result. He looked at Monsanto's escalating warnings to its customers

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tent that the plaintiffs can demonstrate that their exposure stemmed from the *defendants'* PCBs, they will have presented evidence sufficient to survive summary judgment even if their exposure was within background levels—so long as this exposure was sufficient to result in their illnesses.

[37] We cannot separate out the evidence Dr. Nisbet presented regarding the exposure of each of the six plaintiffs because neither side has pointed us to such evidence.

about PCB risks, increasing federal actions on PCBs, improved housekeeping measures by defendant railroads in the early 1980s, emergency measures taken by EPA in the mid 1980s to reduce runoff from the Paoli Railyard, and statements from plaintiffs about steps they took to decrease exposure to PCBs after being warned in 1986. From this information, he concluded that plaintiffs' exposure to PCBs was greatest before 1986.

Dr. Nisbet combined this general assessment of plaintiffs' history of exposure to PCBs with three methods of calculating actual PCB levels: (1) recalculation of blood tests taken by the American Medical Laboratories ("AML"), (2) recalculation of background levels of PCBs, and (3) back calculations of PCB levels in 1986 based on the decay rate of PCBs. The district court held all three methods to be unreliable. We agree with the district court with respect to the first and third methods described below, but conclude that the district court erred in finding Dr. Nisbet's second method unreliable and that it abused its discretion in excluding this opinion.

A. Recalculation of the AML Data

Dr. Nisbet first relied on a recalculation of results of blood tests for PCBs taken by the American Medical Laboratories, Inc. and National Medical Services ("NMS") in 1986 and in 1987. These tests originally showed that plaintiffs' PCB blood levels fell within the general population background PCB levels reported by the laboratory. However, Dr. Nisbet concluded that these tests were inaccurate because the laboratory manager of AML advised him that lab practices in 1986 and 1987 had become sloppy. This was in turn because: (1) AML had used the packed column method, an ostensibly obsolete method of PCB assessment; (2) AML no longer had back up data and had not analyzed samples until a month after they were collected; (3) AML had analyzed blood serum instead of plasma which understates PCB concentrations; and (4) AML's chromatogram showed a PCB pat-

tern that was not consistent with any of the PCB transformer fluids (Aroclors) in the Yard.

Because AML results were two and a half to three times lower than Michigan State Laboratory results for *three unrelated samples in March of 1986* and because Dr. Nisbet thought Michigan State's laboratory was more reliable than AML, he concluded that AML results were generally too low by a factor of two and a half to three. (N 158, 164-68). He therefore *recalculated AML* tests for plaintiffs from August of 1987 by multiplying them by two and a half to three. After such recalculation, the level of PCBs ostensibly present in plaintiffs' blood became far more than background. Defendants challenge this methodology.

The district court found that many of the factual bases from which Dr. Nisbet determined that AML results were inaccurate were themselves inaccurate. It found that the packed column method AML used to assess PCBs was better known than the alternative, that AML did have back up data that Dr. Nisbet could have attained and evaluated, and that AML analyzed the samples a mere two weeks after they were collected. Moreover, tests of AML procedures demonstrated that AML results were generally accurate. The court referenced the testimony of Dr. Whysner who explained that AML had produced results the EPA had found acceptable when EPA spiked samples with PCBs and sent them to AML for analysis in December of 1986; and that AML had produced accurate results for 30 samples sent to it by Washington Occupational Health Associates, Inc. from 1986-92. And, data provided to Dr. Nisbet at the *in limine* hearing (data obtained by Dr. Whysner from AML and Michigan State) demonstrated that the disagreement between AML results and Michigan State results was smaller than he had previously thought.[38]

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[38] Dr. Nisbet admitted that new evidence indicated greater agreement between AML and Michigan State, but he contended that the

The district court went on to find that even assuming a large gap between AML and Michigan State results for the three samples and that the Michigan State results were more accurate, it was not scientifically valid to recalculate results for samples from one laboratory based on a comparison of two laboratories' analysis of three samples a year and a half earlier. Dr. Whysner stated that he had never seen an expert perform such a recalculation. In his view, the problems with this methodology were especially serious given the existence of data showing AML results to be generally accurate, and the existence of data showing that AML and Michigan had produced similar results for PCB samples sent to each laboratory in both October of 1987 and in 1989. Dr. Whysner also stated that there are a variety of explanations for the difference between AML and Michigan State results for the three samples sent in 1986, including the possibility that something happened to the samples during transit.

In light of this evidence the district court concluded that the recalculation rested on a novel scientific methodology that had not been identified in any literature and so had not been subject to critical scrutiny, that it was based on inaccurate assumptions, and ignored inter-laboratory comparison data. The court found that no reasonable scientist in the field of exposure assessment would perform such a calculation. As a result, the district court held Dr. Nisbet's testimony on this matter to be unreliable under Rule 702, and the reliance on the 1986 data from the three samples and the recalibrated 1987 AML results to be data not of the type reasonably relied upon by experts under Rule 703.

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new data showed disagreement between these labs and a third lab. However, disagreement with a third lab hardly provides a justification for multiplying AML results by a factor of two and a half to three. There is no evidence in the record about the extent of the disagreement with the third lab, nor is there evidence that the third lab was more accurate than AML and Michigan State.

We defer to the district court. Recalculation might be acceptable methodologically if there were a series of disagreements of two and a half to three times between two labs over a period of time. However, recalculation based on three samples does not appear reliable. Applying the *Daubert* factors, recalculation itself is not a technique identified in the scientific literature; nor is it generally accepted. To the extent it produces falsifiable results enabling scientists to test whether AML consistently understates its results by two and a half to three times, those results have in fact been falsified by data showing that AML and Michigan State generally produce similar results. And recalculation based on a comparison of three samples is likely often to lead to erroneous results. Although plaintiffs argue that because Dr. Nisbet himself admits that his recalculations are rough estimates he will not confuse the jury, we hold that under *Daubert*, the district court did not err in concluding that the recalculations Dr. Nisbet performed are too rough to be considered reliable at all. Thus, we uphold the district court's exclusion of these recalculations under Rules 702 and 703.

B. *Recalculation of Background*

Dr. Nisbet also believes that, because the background range used by AML was too high, AML results were above background even if the AML results were accurate. Dr. Nisbet opined that the 5 to 30 parts per billion background range used by AML was too high because it relied on studies of unrepresentative populations and because it assumed that the background range had not changed from 1950 to 1990. In reality, according to Dr. Nibet, the PCB background range had declined since 1970 as a result of regulatory efforts and voluntary efforts to reduce PCB use. Apparently, the few longtiudinal studies that have been performed agree that this decline has occurred. Dr. Sherman agreed with Dr. Nisbet that background levels of PCBs have dropped over time.

Rather than relying on the background levels used by AML, Dr. Nisbet decided that background use could best be measured by the National Human Adipose Tissue Survey (NHATS), a nation-wide study which appropriately showed declining PCBs in human fat samples from 1970 to 1983. (N 98-99, 142). However, Dr. Nisbet could not directly compare the NHATS data on the background levels of PCBs in *fat* to the AML data on levels of PCBs in plaintiffs' *blood*. Before attempting such a comparison, Dr. Nisbet had to convert background PCB levels in fat into their equivalent in blood by using a ratio of PCBs in blood in PCBs in fat.

However, the district court found that "experts in the field of exposure assessment do not reasonably rely upon NHATS fat data to calculate background PCB blood levels," and excluded the calculation under Rule 703. The court based its holding on the testimony of Dr. Whysner, who stated that he had never seen experts use NHATS fat data to calculate background levels in blood. Dr. Whysner testified that NHATS reported the background levels in fat in ranges because EPA did not think the data was accurate enough to give average levels; and if it was not accurate enough to give average levels it certainly was not accurate enough to use to convert into blood levels.

To the extent that Dr. Whysner's testimony was that PCB levels in fat could not be used to determine PCB levels in blood, plaintiffs adequately rebutted it. Plaintiffs cite several articles that convert PCB levels in fat to levels in blood (*see, e.g., Luotamo, et al. Assessment of Exposure to PCBs: Analysis of Selected Isomers in Blood and Adipose Tissue*, 54 Env. Reearch 121-34 (1991)) and represent that one of defendants' experts, Dr. Chase, made such a conversion in a 1984 trial at a rate which would lead one to conclude that plaintiffs' blood levels were well above background. It thus appears that the plaintiffs are correct that fat levels are a type of data often used by experts to calculate blood levels, and that

calculating blood levels from fat levels is a reliable methodology.

Dr. Whysner's testimony, however, also called into question whether the *NHATS* fat data is a type of data reasonably relied on by experts to perform such a calculation.[39] Defendants state that while Dr. Chase said that the fat to blood ratio of PCBs could be between 50 to 1 and 500 to 1, he did not say that any estimate was reliable enough to use, and he explicitly stated, like Dr. Whysner, that the NHATS data was not accurate enough to use as a starting point.

Because NHATS data is such a specific type of data, there is little evidence in the literature on whether experts reasonably rely on the particular data. Yet NHATS data is a subset of a type of data reasonably relied on by experts; and thus we are inclined to deem it reliable. *See supra* p. 42 & n. 8, 48 n. 14. Dr. Nisbet, an extremely well qualified expert, thought that NHATS data was a type of data reasonably relied upon, and he provided strong reasons why this data was at least as accurate a source of PCB background blood levels as other studies that analyzed PCB background blood levels directly. Indeed, defendants cite only one or perhaps two (depending on the meaning of Dr. Chase's deposition) experts who have contrary opinions on the reliability of NHATS fat data as a source of conversion to blood levels, and they provide no strong reasons why these experts should be

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[39] As a result, plaintiffs assert that the defendants are only arguing that experts would not reasonably rely on *this* data (NHATS data) as a basis of conversion to PCB blood levels not that experts would not reasonably rely on this *type* of data (fat data). The language of Rule 703 only precludes an expert from relying on *types* of data not reasonably relied on by experts; thus, plaintiffs contend, it was permissible for Dr. Nisbet to rely on NHATS data even if the particular data was imperfect. But we do not rest upon this difficult distinction, for defendants' argument is easily recharacterized as attacking expert reliance on fat data reported in broad ranges (a type of data) rather than as an attack on particular data.

believed as opposed to Dr. Nisbet. Although we review the district court's Rule 703 determination for abuse of discretion, after taking a hard look, the court's conclusion that the (converted) fat data is not reasonably relied upon does not survive the foregoing analysis. Aided by the preference for admissibility of such evidence under the rules, the NHATS data is reliable enough to prove helpful to the jury when converted into background blood levels, and it passes *Daubert* muster. The district court therefore abused its discretion on excluding it.

C. *Back Calculations*

Dr. Nisbet used a third method to calculate PCB exposure prior to 1986. He began with tests of the PCB levels of six plaintiffs in 1992 by the ELI Eco Logic Laboratories, Inc. (Eco Logic), a Canadian scientific consulting firm that performs original research. These tests showed levels of PCBs in plaintiffs' blood comparable to those provided by AML tests in 1986. However, because of precautions taken at the Yard since 1986 to decrease leakage of PCBs, Dr. Nisbet reasoned that plaintiffs' exposure to PCBs had declined since 1986. Thus, he assumed that plaintiffs must have had more PCBs in their blood in 1986 than they had in 1992. By using assumptions about the decay rate of PCBs combined with a model of plaintiffs' exposure to PCBs from non-yard sources, Dr. Nisbet calculated a range of plaintiffs' blood level of PCBs in 1986 from the level in their blood in 1992.

The district court excluded Dr. Nisbet's back calculations as an unreliable methodology for a variety of complicated reasons. One of its reasons was that it concluded under Rule 703, that the Eco Logic data, ostensibly showing the levels of PCBs in plaintiffs' blood in 1992 was a type of data not reasonably relied upon by experts. Because we think that the district court acted within its discretion in precluding Dr. Nisbet from relying on the Eco Logic tests, and that becomes dispositive, we do not

have to reach the issue of the validity of the methodology of performing back calculations.

The district court's Rule 703 ruling had several predicates. First, the court excluded the testimony of Richard Gierczak, plaintiffs' expert on the methodology used by Eco Logic, on the ground of lack of qualifications. It then precluded the admission of the Eco Logic results under Rules 702 and 703, finding that the methodological challenges raised by defense expert Dr. Peterson rendered the results unreliable and unhelpful to the jury. It also ruled that quality control problems rendered the data generated by Eco Logic not of the type reasonably relied on by experts. While the district court erred regarding Gierczak, in view of the balance of our analysis, we must affirm the exclusion of the evidence.

Plaintiffs offered the testimony of Gierczak to defend Eco Logic's methodology. Gierczak has a bachelor's degree and a master's of science degree in medical sciences from McMaster University in Hamilton, Ontario. He currently works as a Senior Project Chemist at Eco Logic. The district court disqualified Gierczak because the only analytic chemistry classes he had taken were as an undergraduate and the 1992 results were the first Gierczak had issued on the congener specific analysis of human blood for PCBs (a method of assessing quantities of specific types (congeners) of PCBs). But the court ignored Gierczak's uncontested testimony that he had been involved in analytic chemistry for "essentially six years. I would include in there graduate work as well, because it was chromatography." [40]

Although the Eco Logic report was the first one Gierczak had *written* on the congener specific analysis of human blood, he had analyzed approximately 50 samples using this method. It is uncontradicted that Gierczak had significant experience performing complicated lab tests,

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[40] Apparently, the only analytic chemistry *courses* Gierczak had taken were as an undergraduate (A 5706).

including the type performed here. Under these circumstances, the liberal qualification standards of Rule 702, *see supra* p. 40, are clearly met;[41] and the district court abused its discretion in ruling Gierczak unqualified. It appears, however, that despite its ruling, the district court considered Gierczak's testimony before concluding that the Eco Logic methodology was unreliable, and hence we turn to the methodological question.

The district court essentially based its conclusion to reject the Eco Logic data on the testimony of Dr. Peterson, who is the Director of Research and Development at Pacific Toxicology Labs in Los Angeles, where he has responsibility for technical matters. Dr. Peterson opined that Eco Logic's methodology was inadequate on several grounds. First, Eco Logic had failed to provide a written protocol describing in detail its method of performing the test (A. 5173). Although Eco Logic provided defendants a written description of the technique Eco Logic had used, Dr. Peterson testified that this description was not detailed enough to qualify as a protocol. Dr. Peterson stated that every reliable laboratory has a written protocol, particularly with regard to a test as complex as congener specific analysis, so that a test is performed the same way each time and so that outside scientists can review the results.

Plaintiffs respond that Eco Logic *did* have such a protocol, that it was published in peer-reviewed scientific journals and that it was set out in Eco Logic's June 15, 1992 report. However, although Gierczak testified that there was a protocol, he qualified his testimony somewhat:

> We have . . . published on two occasions in particular the analysis of congener specific PCBs. So there were protocols that were established, they were modified and we have published those. But as far as a proto-

[41] Of course, even if the district court's exclusion of Gierczak's testimony had been proper, it could have been considered for purposes of determining the *admissibility* of the Eco Logic data—Rule 104(a) determinations do not have to rely on admissible evidence.

> col, because of the size of the lab and the expertise that's available within the laboratory in general, we do not have a large document for each of the particular procedures, and in this case for the analysis of congener specific PCBs. And that's basically because the people are quite well versed and we have access to expert advice.

(Peterson stated that Eco Logic changed the methodology somewhat from that set down in at least one of the cited papers. Thus, Eco Logic did not have a written version of the exact protocol used in these particular tests.

The district court also accepted Dr. Peterson's second criticism of Eco Logic: that essential quality assurance procedures were inadequate for electron capture analysis and mass spectrometry, the two processes Eco Logic used to analyze PCB levels. As quality assurance on its electron capture analysis, Eco Logic tested a lab blank (a sample of laboratory water). Dr. Peterson points out that the lab blank actually produced *higher* results for levels of specific PCB congeners then the values produced for the blood samples from plaintiff Amber Burrell. The higher results made it likely that much of the PCBs found "in" plaintiffs' blood resulted from contamination from the lab. But Gierczak testified that one has to compare *individual* PCB congeners found in the blank with those in the plaintiffs' blood rather than comparing total PCB levels. For the types of PCB congeners likely to have come from the yard, there were 10 to 15 times more congeners present in plaintiffs' blood than were present in the laboratory blank. And, in any case, even the *total* amount of PCBs in each plaintiffs' blood were two to nine times higher than the amount in the laboratory blank.

However, when given a chart formatting the numbers in a new way, Gierczak admitted on cross examination that the level of the specific PCB congeners likely to have come from the Yard was higher in the blank than in the sample for plaintiff Amber Burrell. This makes the Eco Logic electron capture analysis unreliable at least with

respect to Amber Burrell, and we will affirm the district court's ruling that this analysis was inadmissible as to her. It also undermines the reliability of the results for the other plaintiffs as well, because it shows that many of the PCBs quantified in plaintiffs' blood resulted from laboratory contamination.

As for other aspects of quality assurance, the district court found that Eco Logic did not test the "vacutainer blanks" described in the original report sent to Dr. Nisbet and tested only one of three matrix spikes (samples spiked with chemicals similar to but not identical to those being analyzed). Moreover, the matrix spike and the surrogate spikes (samples spiked with the exact type of chemicals being analyzed at set quantities), which should have produced identical recovery rates, produced recovery rates at a ratio of 1:2, which Dr. Peterson said indicated a problem in quantification. The district court also found that the results for both the matrix spike and the surrogate spikes were too high to be of much use as a test, because the spikes were measured in parts per million while the actual samples were measured in parts per billion. Although Gierczak testified that these were minor difficulties which did not undermine confidence in the recovery rates, the district court credited Peterson.

According to the district court, the quality assurance problems present in the electron capture analysis were even more pronounced in the other type of test performed by Eco Logic—mass spectrometry. For the mass spectrometry test, neither matrix nor surrogate spike samples were even analyzed, leading Dr. Peterson to conclude that, "[i]n absence of [this] recovery data, I don't think you can be confident in the results here."

Moreover, Eco Logic failed to calibrate the instruments it used for both electron capture analysis and mass spectrometry within the range occupied by plaintiffs' samples. In other words, while Eco Logic made sure that its instruments were set accurately within a certain range of

PCB detection, the readings on plaintiffs' samples ended up being outside of this range. Peterson stated that the fact that plaintiffs' samples fell outside the calibrated range made the analysis "less accurate" because it is difficult to tell how the instrument will behave at low levels of PCBs.

Gierczak responded to Peterson by explaining that the calibration was accurate if extended in a linear fashion beyond the range that had been specifically set, as long as the level of PCBs being measured was not so small that it was close to the limit of the machine's ability to detect PCBs. According to Gierczak, plaintiffs' samples were within the range at which the calibration was accurate. Again, the district court credited the testimony of Peterson rather than Gierczak.

Finally, the district court accepted Peterson's assertion that Eco Logic did not adequately confirm its electron capture results. In the electron capture analysis, the DB 17 column is used to confirm the identities of PCB congeners found on the DB 5 column where the quantific takes place.[42] Peterson stated that confirmation on the DB 17 column of each individual peak formed by a congener on the DB 5 column is necessary to ensure that individual congeners are not misidentified as other chemicals. Defendants point out that Gierczak "admitted" that the DB 17 column is "absolutely critical to the overall analysis," yet Gierczak was unable to state whether any of the 15 PCB congeners Eco Logic had found on the DB 5 column had also been identified in the DB 17 column.

Plaintiffs respond that when Gierczak testified that the DB 17 column is critical to the analysis, what he demonstrated is that the DB 17 column is critical *for the purpose of* establishing a qualitative check to determine the pres-

[42] There is no further information in the record as to what the DB 5 and DB 17 columns are: thus, we assess the importance of use of the DB 17 column solely based on the assertions of the experts as to its importance.

ence of PCBs. He stated that Eco Logic had performed such a qualitative check by engaging in a statistical analysis of 32 PCB congeners to confirm the presence of PCBs on both columns. This made comparison of individual peaks in the two columns unnecessary. Gierczak also testified that an individual comparison was not necessary to ensure that Eco Logic was measuring only PCBs and not some other compound, because Eco Logic's equipment was calibrated using a pure PCB standard. Dr. Nisbet, for his part, testified that *he* confirmed the presence of *specific* congeners by comparing chromatograms of the two columns combined with independent knowledge of where the specific peaks should be. But the congeners Dr. Nisbet relied on to make his back calculations were in fact not found in the DB 17 column results, (NT at 127-30), and the district court pointed out that the quality control manual submitted by Eco Logic says that, "[t]he presence of an analyte is confirmed only when identified on both columns." Thus still another factor supports the court's conclusions.

The district court pointed to one final methodological problem in Eco Logic's tests. It noted that the mass spectrometry and the electron capture analysis produced inconsistent results for congeners that were measured by each. Dr. Peterson testified that this points to a problem in accuracy. The district court also found that Eco Logic's report on the six plaintiffs' PCB blood levels was the first ever issued on PCB congener specific analyses of human blood samples. The novelty of Eco Logic's approach, combined with Eco Logic's flaws in quality control, led the district court to exclude the Eco Logic data under Rules 702 and 703.

Applying the *Daubert* factors, we think that whether the district court acted within its discretion in excluding this evidence is a close question. The analysis performed by Eco Logic is testable (one can verify whether the lab produces inaccurate results for samples with known levels

of PCBs); Eco Logic has published two peer-review articles about the analysis (though presumably without the specific level of quality controls present here); and, while novel, defendants do not actually challenge this methodology overall but only the quality controls employed in these particular tests. Moreover, Gierczak provides a fairly convincing defense of the quality control measures, and surely any complicated procedure will be subject to some criticisms. Dr. Nisbet, a well-qualified expert, testified that "In spite of the criticisms by Dr. Peterson and Dr. Kaley, I remain satisfied that those results are reliable, and can be used in the way that I have used them to support my conclusions."

Nonetheless, we hold that the district court acted within its discretion in excluding the Eco Logic results. Dr. Peterson, who oversees the technical aspects of a major laboratory, testified that Eco Logic had failed to perform many *standard* quality control techniques, and that those they had performed cast substantial doubt on their results. He concluded that the combinations of those flaws were so great as to render the data produced by Eco Logic unreliable. The purpose of an *in limine* hearing is to develop evidence on reliability of scientific evidence. Here there was an extensive hearing and a plethora of testimony justifying the district court's conclusion. Although as we have explained, a number of *Daubert* factors (and the general policy of the federal Rules) favor admissibility, we cannot say that a conscientious district judge could not credit a qualified witness such as Peterson that the quality control and methodological flaws were not minor problems but were so great as to undermine the data to the extent that it may not reasonably be relied on by experts in the relevant field and would be unhelpful to the jury. The ruling of the district court will therefore be affirmed.

D. *Remaining Issues*

Plaintiffs assert that there was *no* justification for the district court's total exclusion not only of Dr. Nisbet's testimony based on the three methods of calculating PCB exposure, but of the balance of it as well. For Dr. Nisbet also opined as to human epidemiological studies and animal studies showing causal links between PCBs and disease. He testified that the AML results themselves showed PCB levels above background levels (though on what basis he was calculating background is unclear), and that AML's chromatograms show, especially for the Burrell plaintiffs, a pattern that is consistent with their having had significantly higher exposure at a prior date. Dr. Nisbet testified that the assumption that plaintiffs' blood was within background levels was based on studies of people who had occupational or residential exposure to PCBs, not studies of members of the general public with average PCB exposure, (A673, 675, 4181), and that a 1987 exposure study (ATSDR) showed PCB levels much higher than background for 89 Paoli residents despite the ATSDR conclusion to the contrary. Finally, Dr. Nisbet testified that plaintiffs had a significant risk of developing illnesses in the future. Plaintiffs are correct that the district court provides no justification for excluding any of this testimony and that it must therefore be admitted.

E. *Conclusion*

We will uphold the district court's exclusion of Dr. Nisbet's recalculation of AML lab tests and of his back calculations based on the Eco Logic data. However, we will reverse the court's exclusion of Dr. Nisbet's analysis of background levels based on his conversion of the NHATS fat data into blood levels; we will also reverse the district court's exclusion of the remainder of Dr. Nisbet's testimony. Thus, at least with respect to those plaintiffs for whom Dr. Nisbet testified, including the two who have viable personal injury claims, Dr. Nisbet's provides sufficient evidence of exposure to defendants' PCBs

(by testifying that the AML blood tests showed levels above background) for them to survive summary judgment on the exposure issue.

VIII. THE HARMFULNESS OF THE CHEMICALS

A. *Introduction*

The plaintiffs advanced several types of evidence to demonstrate that PCBs are harmful, including the testimony of Drs. Sherman and DiGregorio that the illnesses of specific plaintiffs were caused by PCBs, some limited epidemiological studies to which Dr. Nisbet testified, animal studies on the health effects of PCBs, and incidents at Yusho and Yu Cheng in which many individuals were exposed to substantial amounts of PCBs and became ill. The plaintiffs also presented evidence that they had been exposed to chemicals other than PCBs arising from the Yard (e.g. furans and dioxins) and that these chemicals were dangerous.

In addition to excluding the testimony of Drs. Sherman, DiGregorio and Nisbet as detailed above, the district court excluded animal studies on the health effects of PCBs, data on any chemicals other than PCBs, and any data stemming from the incidents at Yusho and Yu Cheng. We have already reversed the district court's exclusion of Dr. Nisbet's testimony on epidemiological studies. For the reasons that follow, we will also reverse the district court's exclusion of the animal studies but will uphold its exclusion of non-PCB related data (data on furans and dioxins) and data from the Yusho/Yu Cheng incidents.

B. *Animal Studies*

The district court found animal studies to be irrelevant under Rule 402. The court also found use of the data to be unreliable, presumably under Rule 703, and that "use of that data would tend to mislead or confuse the jury and would be of no assistance to the jury in deciding the

issues in this case," thereby presumably invoking Rules 702 and 403. In reaching these conclusions, the district court relied on the testimony of Dr. Robert C. James, an Associate Professor at the Center for Environmental and Human Toxicology at the University of Florida. Dr. James asserted that test animals are often very sensitive to chemicals due to breeding, overeating, and physiological, biological and metabolic pathways which are different than those of humans. Dr. James also explained that test animals are given extremely high doses of the chemicals. Thus, studies of test animals identify many chemicals as carcinogenic in animals that are not carcinogenic in humans (James T. 91-92). Apparently crediting Dr. James, the district court found that use of animal studies as a basis for reaching a conclusion on causation of adverse health effects in humans is unreliable *when that data is contradicted by significant epidemiological data in humans.*

However, the district court did not cite any evidence demonstrating that significant epidemiological data contradicted the animal studies.[43] And Dr. Nisbet cited some occupational studies that he concluded supported the animal studies. According to Dr. Nisbet, these studies showed that exposure to PCBs caused elevated levels of enzymes associated with liver damage, skin irritation, the early forms of chloracne, elevated lipids, and skin, liver and

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[43] The court did point to Dr. James' testimony that "the consensus opinion is that chloracne is the only conditional disease that is known to [be causally] associated with occupational PCB exposure." (JA 5570). But, even if uncontradicted, this statement only indicates a lack of epidemiological studies definitively showing that PCBs do cause various diseases: it does not identify data showing that PCBs do not cause various diseases. As Dr. Molholt, an EPA toxicologist, explains, "human epidemiologic studies have not *conclusively* linked PCB exposure to any significant human disease, i.e., the studies thus far have been inconclusive. How can inconclusive studies constitute strong evidence [that PCBs do not cause disease]?" JA 4078 (emphasis added).

pancreatic cancer.[44] Additionally, an article by Dr. Nicholson explains that when there is a concordance of animal data and human data, it strengthens the reliability of each.

Moreover, Dr. Nisbet testified that scientists routinely use animal studies to assess risks of chemicals to humans. Even defendants' own experts based their opinions partly on animal studies showing that they are at least relevant to assessing causation in humans. *See e.g.* Dr. Kelly's testimony. Dr. Nisbet added that animal studies are particularly valuable with respect to assessing health effects of PCBs, because humans and monkeys have shown similar sensitivity to PCDFs and thus are likely to show similar sensitivity to PCBs.[45] Finally, EPA has relied on animal studies to draw conclusions about the effects of PCBs on humans.

Dr. Molholt, EPA's toxicologist at the Yard, explained:

> in the absence of epidemiologic proof, this statement [criticizing animal studies] implies that PCBs are exonerated. No! In the absence of epidemiologic proof in humans we must drop to our second tier in the understanding of human carcinogenic prediction: Animal testing. And there the scientific evidence is conclusive.

Molholt adds that "PCBs are not only considered as 'potential' human carcinogens, but as *probable* human carcinogens (Class B) by the Agency on the basis of

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[44] The studies themselves were not provided in the record.

[45] Defendants argue that Dr. Nisbet's testimony on the relevance of animal studies is itself irrelevant because Dr. Nisbet's testimony was deemed generally inadmissible. However, even if Dr. Nisbet's tesitmony about the level of PCBs in plaintiffs' blood was properly excluded, and we have held that it was not, there would be no justification for excluding his testimony about animal studies. Nor does his testimony have to be admissible for it to be relevant to determining the admissibility of animal studies. *See* Fed. R. Evid. 104(a).

conclusive experiments in test animals." In fact, EPA thinks that PCBs have the same carcinogenic potency as vinyl chloride, which is one of only 14 chemicals that EPA has indicated have been proven to be carcinogenic by epidemiological studies. The "more probable than not" standard employed by EPA is the same standard that is employed in civil litigation.

The case law on the admissibility of animal studies in various contexts is mixed.[46] Many cases have held that the studies are admissible. *See, e.g., In re Bendectin Products Liability Litigation*, 732 F. Supp. 744, 749 (E.D. Mich. 1990) (experts in the field think that it is reasonable to rely on non-epidemiological studies to link Bendectin to birth defects); *Hagen v. Richardson-Merrell, Inc.*, 697 F. Supp. 334, 337 (N.D. Ill. 1988) (defendants did not adequately demonstrate that expert opinion based partly on animal studies should be excluded); *Saakbo Rubanick v. Witco Chemical Corp.*, 576 A.2d 4, 7, 15 (N.J. Super. 1990) (under New Jersey law reversing trial court's exclusion of expert testimony, which was partly based on animal studies, that PCBs caused cancer). In *Villari v. Terminix International, Inc.*, 692 F. Supp. 568, 570 (E.D.Pa. 1988), Judge Pollak explained that:

> While it may be true that defendant can offer tests and experiments that do not support the findings of plaintiffs' experts, the defendant cannot deny that animal studies are routinely relied upon by the scientific community in assessing the carcinogenic effects of chemicals on humans. Even defendant's own expert acknowledges that animal experiment studies are built on 'prudent presumptions,' although he concludes that they should not be admitted.

While other cases have held that animal studies are inadmissible, these cases are for the most part distinguish-

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[46] All of these cases were decided prior to *Daubert*.

able because most involved the exclusion of animal studies in the face of *extensive* epidemiological data that failed to support causation, because none involved studies on animals particularly similar to humans in the way they react to the chemical in question, and because none involved studies the federal government had relied on as a basis for concluding the chemical was a probable health hazard. *See In re "Agent Orange"*, 611 F. Supp. at 1241 (excluding animal studies of Agent Orange based partly on the court's earlier conclusion that there was significant contrary epidemiological data, that the Center for Disease Control had concluded that the animal studies did not demonstrate adverse human health effects, and that the animal studies gave pregnant females high doses at critical times) (citing *In re "Agent Orange" Product Liability Litigation*, 603 F. Supp. 239, 246-47 (1985) (*"In re "Agent Orange" I"*)); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420 (5th Cir. 1987) (excluding the evidence where there was only a single animal study of picloram and it showed a link to a disease completely different than plaintiff's diseases); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 830 (D.C. Cir. 1988) (excluding animal studies of Bendectin because of the overwhelming body of contrary epidemiological evidence and the admissions of the expert that animal studies merely raise a suspicion of causation in humans); *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190, 1194 (1st Cir. 1987) (excluding animal studies of Bendectin where they stood in face of significant contrary epidemiological data); *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.) (excluding the testimony where the record failed to make clear how the animal studies were sufficient to show that Bendectin causes birth defects more probably than not), *cert. denied*, 113 S. Ct. 84 (1992).[47]

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[47] We recognize that while all of these cases are somewhat distinguishable on their facts, both *In re Agent Orange* and the district court in *Lynch* to some extent did rely on general problems

Here, where the EPA has relied on animal studies to conclude that PCBs are a probable human carcinogen, where there is reason to think that animal studies are particularly valuable because animals react similarly to humans with respect to the chemical in question, and where the epidemiological data is inconclusive and some of it supports a finding of causation, we think that the district court abused its discretion in excluding the animal studies. Certainly, the evidence meets the relevance requirements of Rule 402 and we think, after taking a hard look, that it also meets the reliability requirement of Rules 702, 703 and 403.

Applying the *Daubert* factors, animal studies themselves are testable (the hypothesis that PCBs cause a particular disease can be verified or disproven in the particular animal study, in other animal studies, or in human epidemiological studies). Animal studies follow a generally accepted methodology (all of the experts who testified here accepted the methodology for the purpose of proving whether a particular chemical is harmful in animals). They have been peer reviewed (the studies referred to by experts in this case were published in peer review journals). They are used for purposes outside of litigation. Finally, although their "fit" to proof of causation in humans is in dispute, all experts acknowledge they are of some use—at least in eliminating those chemicals not likely to cause disease in humans. Given the specifics of the animal studies here, the district court should not have excluded the studies as based on unreliable data and as unhelpful.

The district court also abused its discretion in concluding that the probative value of the animal studies was substantially outweighed by unfair prejudice and waste of time. The court said nothing about why expert reliance

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with extrapolating from animal studies in excluding such studies. *See In re Agent Orange*, 611 F. Supp. at 1241; *Lynch v. Merrell-National Laboratories*, 646 F. Supp. 856, 866 (D. Mass. 1986).

on animal studies is more prejudicial than any other scientific studies as we required in *Downing*, and there is significant evidence in the record from sources such as the EPA that the evidence is quite probative with respect to PCBs. In *Paoli I* we said with respect to the district court's exclusion of animal studies under Rule 703 that "It is not clear that the court was not merely choosing between opinions as opposed to excluding plaintiff's opinion on evidentiary grounds." *Paoli I*, 916 F.2d at 853. On this point the district court still seems to be choosing between opinions. We therefore hold that the animal studies pass *Daubert* muster, are admissible, and are one source by which plaintiffs can prove the harmful effects of PCBs.

C. *Exposure to Dioxins and Furans*

Plaintiffs assert that in addition to being exposed to PCBs, they were exposed to dioxins and furans.[48] The district court, however, excluded testimony regarding chemicals other than PCBs. It also found that the plaintiffs could not demonstrate that they had been exposed to dangerous quantities of dioxins and furans; it thus excluded evidence regarding these chemicals as irrelevant under Rule 402 and as substantially more unfairly prejudicial and likely to cause undue delay than probative under Rule 403. We affirm.

Plaintiffs point to evidence showing that furans can be present in unused transformer fluids at up to 20 parts per million and at still higher levels in waste transformer fluids. Furthermore, they note, PCB-based transformer fluids produce still more dioxins and furans when heated,

[48] Plaintiffs also claimed that they had been exposed to epoxide dicylodiepoxy carboxylate and tin tetraphenyl. The district court found that while tin tetraphenyl and EDDC did exist as a small percentage of the dielectric fluid in the Yard, no soil or blood or tissue samples were ever tested to show the presence of these chemicals in or near the plaintiffs, and excluded the evidence. The plaintiffs do not challenge that ruling on appeal.

see Literature Review of Pyriolysis and Combustion Products of Selected Utility Materials, (Nov. 1986), and affidavits show there were various heat producing activities that took place at the Yard. Plaintiffs then argue that it is reasonable to conclude that these furans and dioxins leaked from the Yard onto plaintiffs' soil, because a worker spread waste transformer fluids from the drums directly on the parking lot, and that some of these fluids, if they followed normal water run off patterns, would have entered plaintiffs' yards. Dr. Kopstein buttressed the plaintiffs' argument. He explained that "fires at the yard would had to have produced furans and dioxins;" as a result, he "concluded that . . . there was an ongoing and continuous release of PCBs and most likely to a reasonable—within a reasonable degree of scientific certainty furans and dioxins, into the neighborhood during that 35-year period."

The district court found that, although dioxins and furans *were* measured in the Yard, they were measured in quantities below the Center for Disease Control's ("CDC") level of concern. Because soil in the Yard was the only sample of any sort tested for dioxins and furans, the district court found the soil readings in the Yard to be basically conclusive of the fact that dioxins and furans were not present in sufficient quantities to injure. The court was not moved by Dr. Kopstein's testimony, because he could not quantify exposure due to the absence of data on soil concentration off the site. Furthermore, the court cited the testimony of Dr. James who stated that the dose of a chemical a person takes into his or her body cannot be calculated very well from the amount of chemical to which they have been exposed. Thus, because it concluded that plaintiffs had not been exposed to enough dioxins and furans to cause injury, the court ruled that evidence about these chemicals should be excluded under Rule 402 as irrelevant and under Rule 403 as substantially more (unfairly) prejudicial than probative and as likely to cause undue delay.

Plaintiffs respond to the district court's rulings by arguing that the soil sample showing levels of dioxins and furans at levels below CDC concern was from only 10 inches of soil on the 28 acre railroad yard and thus should not be given the dispositive weight accorded to it by the district court. Although plaintiffs do not contest the district court's finding that they cannot quantify their furan intake, they assert that the importance of lack of quantification is a matter for the jury to decide. They cite three cases in which courts refused to grant summary judgment despite plaintiffs' inability to quantify exposure to chemicals at levels sufficient to cause disease. *See Junge v. Garlock, Inc.* 629 A.2d 1027, 1029-30 (Pa. Super. 1993) (holding that an expert's testimony that asbestos at plaintiff's job was a substantial factor in causing his asbestosis was admissible despite the inability of the expert to quantify plaintiff's exposure; this was true despite testimony that defendants' asbestos only emitted a low level of dust); *Ferebee v. Chevron Chemical Co.*, 552 F. Supp. 1293, 1298 (D.D.C. 1982), *aff'd* 736 F.2d 1529 (D.C. Cir. 1984), *cert. denied* 469 U.S. 1062, 105 S. Ct. 545 (1984); *Ruiz v. Minnesota Mining and Manufacturing Co.*, 93 Cal. Rptr. 270, 273-74 (Cal. App. 1971).

It would seem that, in making an overall assessment of the likelihood that plaintiffs' injuries were caused by activities at the Yard, evidence about furans and dioxins is at least minimally relevant. It is not clear why the CDC levels are definitive evidence of safe levels. Nor is it clear that the level plaintiffs were exposed to was below CDC levels. Plaintiffs raise significant questions about the reliability of the soil samples at the Yard.[49] But, while

[49] Plaintiffs also cite the testimony of Dr. Bruce Molholt, the EPA's toxicologist working at the Yard, who stated that "a preliminary sampling for PCDFs has turned up contamination in the area of concern three times the equivalence deemed a soil action level by CDC." (JA 4078). Plaintiffs provide no indication as to whether this preliminary estimate was later revised, which significantly weakens the value of this testimony.

we think that the evidence would pass muster under Rule 401, *see Williams v. West Chester*, 891 F.2d 458, 466 (3d Cir. 1989), which has a low threshold relevancy, we think that the district court acted within its discretion in excluding this evidence under Rule 403.

The probative value of plaintiffs' evidence is lower than in the cases plaintiffs cite above. In *Junge*, for example, defendants submitted no evidence that the level of asbestos in defendants' plant was too low to cause injury. Here, defendants have submitted evidence showing that the furans produced were below CDC levels of concern. Moreover, it seems more reasonable to conclude that the *asbestosis* at issue in *Junge* was caused by a low level of *asbestos* on defendants' property than to conclude that the various illnesses here were caused by low levels of furans on defendants' property. There are fewer alternative causes of asbestosis than there are alternative causes for the injuries being attributed to furans. Finally, we note that neither *Junge*, nor the two non-Pennsylvania cases cited by plaintiffs, involved circumscribed appellate review of a trial court decision excluding evidence.

The district court was within its discretion in holding that the minimal relevance of this evidence was substantially outweighed by its potential for unfair prejudice and thus should be excluded under Rule 403. Given that there is little evidence that plaintiffs' exposure to furans or dioxins was significant, the district court properly held that admitting evidence that plaintiffs were exposed to these chemicals as well as evidence about the significant negative effects of these chemicals would have been too inflammatory for the jury. This is especially true given the negative publicity that dioxin (Agent Orange) has received and that currently many experts think furans are significantly more dangerous than PCBs. *See also* the discussion of prejudice regarding the Yusho, Yu Cheng incidents *infra* pp. 124-125. Moreover, allowing in evidence regarding chemicals other than PCBs would create the need

to have mini-trials on plaintiffs' exposure to each of these chemicals and the harm they cause; this would cause "undue delay" given the minimal relevance of the evidence. Fed. R. Evid. 403.[50]

IX. THE YUSHO AND YU CHENG INCIDENTS

The district court also precluded admission of evidence about the incidents at Yusho, Japan, and Yu Cheng, Taiwan, where individuals were exposed to both furan- and PCB-contaminated cooking oil. *See Paoli I*, 916 F.2d at 840, 854. Plaintiffs relied on these incidents as part of their evidence that both PCBs and furans are hazardous to humans, because after both incidents there were outbreaks of various illnesses within 20 to 150 days.

The district court, however, cited several studies and the testimony of Dr. James for the proposition that furans rather than PCBs were the primary agent responsible for the illnesses at Yusho and Yu Cheng. Dr. James noted that the pattern of illnesses at Yusho and Yu Cheng has not been duplicated in workers exposed only to PCBs; moreover, the victims at Yusho and Yu Cheng remained ill when their PCB levels, but not their furan levels, returned to normal. The district court concluded that plaintiffs' lack of exposure to furans combined with the fact that the pattern of illnesses in Paoli residents were not similar to those at Yusho and Yu Cheng made these incidents irrelevant. Furthermore, the court added that the prejudicial effect of (admitting evidence on these incidents would be high, because the incidents "concern a widespread poisoning caused by a substance to which Plaintiffs cannot establish they were exposed."

Plaintiffs contend that the district court should have admitted evidence about Yusho and Yu Cheng even if

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[50] Although we have been cautions in permitting pretrial exclusion on Rule 403 grounds, here the record was sufficient extensive to permit its application.

plaintiffs' evidence that they were exposed to furans is excluded. Plaintiffs cite Dr. Nisbet's testimony that Yusho and Yu Cheng provide important evidence about *PCBs* because these incidents involved human exposure to significant quantities of PCB and thus show the manner in which PCBs are distributed in the body and their half lives. Dr. Nisbet added that, by providing evidence about furans, Yusho and Yu Cheng provide evidence on the health effects of PCBs. This is because furans and PCBs have similar chemical structures, act by the same mechanisms, and have similar toxicity. Plaintiffs also cite the testimony of Dr. Kenneth Chase, one of defendants' experts who testified to the structural similarity and comparable toxicity of furans and PCBs. In fact, Dr. Chase asserted that "probably one of the biggest developments [in the history of PCBs] that ever took place was Yusho."

As with the contention that plaintiffs were exposed to furans and dioxins, we hold that the district court improperly excluded evidence concerning Yusho and Yu Cheng as irrelevant, given the low threshold of relevancy of Rule 401. We think that it was relevant to the effects of PCBs both by showing possible harms of PCBs directly and indirectly (by showing harms of furans which are structurally similar to PCBs). Dr. Nisbet and Dr. Chase both testified to this. As we held in *Paoli I*, the district court cannot exclude evidence with respect to Yusho and Yu Cheng based on its conclusion that there is a "consensus" that Yusho and Yu Cheng are irrelevant in analyzing the effects of PCBs. The court, we noted, has not pointed to evidence showing the existence of such a consensus. *See Paoli I*, 916 F.2d at 854; *cf. id.* at 858 (holding that evidence that PCBs cause liver cancer is probative of the fact that PCBs cause other forms of cancer and so is admissible even in the absence of plaintiffs with liver cancer).

That said, we hold that the district court was within its discretion in concluding that the prejudicial effect of

evidence about Yusho and Yu Cheng is attended by unfair prejudice that outweighs its probative value given that the relationship of PCBs to the illnesses of the victims in the two incidents is attenuated and given the risk that the jury would be unduly influenced by the illnesses of the numerous victims—illnesses largely caused by furans rather than PCBs. Moreover, development of evidence about Yusho and Yu Cheng would be a significant waste of time due to their limited relevance, requiring mini-trials on the exposure, types of illnesses, and causes of illnesses of individuals during these incidents.

X. THE PLAINTIFFS' PERSONAL INJURY CLAIMS —SUMMARY AND CONCLUSION

As a result of our review of the district court's admissibility decisions, we reverse its grant of summary judgment with respect to those present injury claims of Bessie Cunningham and Amber Burrell, as we have detailed above, *see supra* p. 88, 90. We affirm the district court's grant of summary judgment on all of the other personal injury claims.

Those plaintiffs for whom Dr. Nisbet testified, including both Bessie Cunningham and Amber Burrell, presented sufficient evidence to survive summary judgment on the exposure issue. Although we have upheld the district court's exclusion of much of Dr. Nisbet's testimony, we have reversed its exclusion of his recalculation of background levels using NHATS fat data. Based on this recalculation, Dr. Nisbet concluded that the levels of PCBs in plaintiffs' blood were above background. This testimony, especially when combined with soil samples of PCBs in plaintiffs' yard at levels EPA does not consider safe and with evidence that the plaintiffs played in those yards and ate vegetables grown in those yards, constitutes sufficient evidence of exposure.

Bessie Cunningham and Amber Burrell also presented sufficient evidence of the harmful effects of PCBs and that

PCBs caused many of their particular illnesses. While we have upheld the district court's exclusion of evidence concerning chemicals other than PCBs and of evidence related to Yusho and Yu Cheng, we will reverse the district court's exclusion of animal studies on the effects of PCBs. The animal studies combined with Dr. Nisbet's testimony with respect to epidemiological studies and Dr. Sherman's testimony that, given her review of the literature, her consideration of illnesses in the Paoli population, and her review of the medical examinations and histories of Bessie Cunningham and Amber Burrell, the illnesses of these two particular plaintiffs were caused by PCBs, constitutes sufficient evidence for a reasonable jury to find defendants liable. Thus, we will reverse the district court's grant of summary judgment on those present injury claims of Bessie Cunningham and Amber Burrell.

We will, however, affirm the district court's grant of summary judgment with respect to the present injury claims of all of the other plaintiffs. Because the district court acted within its discretion in excluding the testimony of Drs. Sherman and DiGregorio that PCBs caused the particular illnesses of these plaintiffs, they have no admissible evidence on causation. Thus, the district court's grant of summary judgment was proper.

XI. THE MEDICAL MONITORING CLAIMS

All of the plaintiffs except James Lament have brought claims for medical monitoring that will enable early detection and prompt treatment of any PCB related diseases. Many of the plaintiffs have also brought claims for fear of disease and increased risk of disease. We consider first whether medical monitoring is cognizable in Pennsylvania, second, what the elements of the cause of medical monitoring are, and third, whether the plaintiffs have provided sufficient admissible evidence to make out such a claim.

A. *Medical Monitoring as a Viable Claim.*

In *Paoli I* we attempted to predict the holding of Pennsylvania courts on a claim for medical monitoring. We concluded that such a claim was cognizable under Pennsylvania law. Defendants argue that subsequent Pennsylvania decisions undercut our conclusion that medical monitoring is a viable cause of action in Pennsylvania. The district court declined to decide the issue because it found that, in any case, there was not enough evidence to prove a claim for medical monitoring. We disagree. We think that medical monitoring is still a viable claim under Pennsylvania law and that the plaintiffs have presented sufficient evidence to survive summary judgment on that claim.

Defendants point to several cases as precluding the viability of medical monitoring claims in Pennsylvania. In the first of these cases, *Marinari v. Asbestos Corp.*, 612 A.2d 1021, (Pa. Super. 1992), an en banc Pennsylvania Superior Court adopted the "two-disease approach" to asbestos litigation. Under this approach, asbestos plaintiffs do not need to bring claims for possible future injuries at the same time they bring claims for present injuries. Plaintiffs do not have to, and in fact cannot, bring claims for a risk of future cancer at the time they sue for a disease they already have. They must bring their cancer claim only if and when they actually contract cancer. The *Marinari* court reasoned that adjudicating future risk of disease is too speculative and would result in undercompensation for some plaintiffs and overcompensation for other plaintiffs. *See id.* at 1026.

In *Morrison v. Fibreboard Corp.*, 630 A.2d 436, 437-38 (Pa. Super. 1993) and *Higginbotham v. Fibreboard Corp.*, 630 A.2d 14, 15-16 (Pa. Super. 1993), Pennsylvania courts interpreted *Marinari* to rule out claims for damages based on fear of future injuries as well as risk of future injuries—they stated that any distress arising out of fear

of cancer can be compensated at the time that malignancy occurs.[51]

Defendants argue that *Marinari* and related case law precludes the plaintiffs from bringing medical monitoring claims. Although none of these cases specifically addresses such claims, defendants assert that such claims are excluded by the language of the opinions. In explaining why plaintiffs could not bring claims for risk of a future disease, the *Morrison* court explained that this was "[b]ecause the *Marinari* Court, however, found juries must now base their verdicts not upon sheer speculation as to possible future damages, but rather upon only empirical or physically objective evidence of present injury." 630 A.2d at 437. Similarly, in *Ottavio v. Fibreboard Corp.*, 617 A.2d 1296, 1302 (Pa. Super. 1992) (en banc), the Superior Court stated that, "In an action for exposure to asbestos, a plaintiff's claim may encompass only the harm caused by the diseases which have become manifest." The defendants argue that because medical monitoring is a claim that arises before a disease has "become manifest," before there is "empirical or physically objective

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[51] In addition to claims for medical monitoring, some plaintiffs have brought claims for increased fear and risk of disease. We are satisfied that the Pennsylvania Supreme Court would follow the lead of the strongly reasoned Superior Court decisions in *Marinari*, *Morrison*, and *Higginbotham*. Thus, under current Pennsylvania law, the plaintiffs in this case have no cause of action for risk or fear of future injuries. We will therefore not spend further time discussing these claims but will affirm the district court's grant of summary judgment on all of them.

Plaintiffs cite *Hackney v. Woodring*, 622 A.2d 286 (Pa. Super. 1993) for the proposition that there is no need for expert testimony on a plaintiff's level of distress is accurate, but that case assumes that plaintiffs have made out the other elements of a claim of intentional infliction of emotional distress, and *Morrison* and *Higginbotham* make clear that toxic tort litigation is not the type of situation in which such a claim is applicable.

We therefore have no need to evaluate the district court's conclusions that Dr. DiGregorio's and Dr. Schecter's testimony on fear of disease is inadnissible.

evidence of present injury," medical monitoring is not a viable claim in Pennsylvania.

One Pennsylvania Court of Common Pleas has explicitly agreed with the defendants. *See Addams v. Westinghouse Electric Corp.*, No. 1340 C.D. 1988, slip op. at 16 (Pa. Ct. Com. Pleas, Mercer County, July 30, 1993) ("Based on *Marinari*, and the two-disease rule, this Court feels an action for medical monitoring is inappropriate. . . . [A] cause of action for future risk of cancer does not exist, the same policy issues underlie both actions."). And, according to the defendants, one Superior Court panel has implicitly agreed with their reading of Pennsylvania law. *Giffear v. Johns-Manville Corp.*, 632 A.2d 880 (Pa. Super. 1993) (holding that claims for asymptomatic pleural thickening caused by exposure to asbestos were not cognizable).[52]

To support their reading of *Giffear*, the defendants point to Judge Del Sole's concurrence, in which he asserted that, "the majority wrongly assumes that a person with asymptomatic pleural thickening has no damages . . . . [O]nce one is diagnosed with pleural thickening, there may be medically necessary reasons for increased medical monitoring of the lungs to provide early detection of cancer." *Id.* at 890 (Del Sole, J., concurring). Defendants argue that by failing to address the concurrence's claim that asymptomatic pleural thickening might sometimes justify a claim of medical monitoring and by holding that asymptomatic pleural thickening does not give rise to a cognizable claim, the majority implicitly ruled that medical monitoring claims are never justified.

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[52] *Giffear* did rule out claims for present injuries that are asymptomatic. We have no reason to believe that the Pennsylvania Supreme Court would reach a different result. Thus, in discussing plaintiffs' claims for present injuries, *supra*, we affirmed the district court's grant of summary judgment on plaintiffs' asymptomatic "injuries."

However, while the course the Pennsylvania courts have taken since *Paoli I* casts some doubt on whether they would accept a medical monitoring claim, it does not cause us to change the conclusion that we reached in *Paoli I* that Pennsylvania would recognize such a claim. "[I]n the absence of a *clear* statement by the Pennsylvania Supreme Court to the contrary or other persuasive evidence of a change in Pennsylvania law, we are bound by the holdings of previous panels of this court." *Smith v. Calgon Carbon Corp.*, 917 F.2d 1338, 1343 (3d Cir. 1990), *cert. denied*, 499 U.S. 966, 111 S. Ct. 1597 (1991). No such "clear statement" or "persuasive evidence" exists here.

The *Giffear* majority was not addressing a claim for medical monitoring and made no reference to Judge Del Sole's concurrence. Thus, no Pennsylvania court other than the single trial Court in Mercer County has directly addressed the medical monitoring question. And although some language in Superior Court decisions since *Paoli I* seems to exclude medical monitoring claims, the policy concerns behind those decisions do not.

Both *Morrison* and *Higginbotham* were based on the Superior Court's concern that actions for fear of cancer, like actions for risk of cancer, involve significant speculation as to damages. However, the Pennsylvania courts' worries about speculative verdicts is the same worry they expressed in placing limitations on claims for risk of future injuries in *Martin v. Johns-Manville Corp.*, 494 A.2d 1088 (Pa. 1985).

In *Paoli I*, we distinguished *Martin* by saying that:

> The injury in an enhanced risk claim is the anticipated harm itself. The injury in a medical monitoring claim is the cost of the medical care that will, one hopes, detect that injury. The former is inherently speculative because courts are forced to anticipate the probability of future injury. The latter is much less speculative because the issue for the jury is the

> less conjectural question of whether the plaintiff needs medical surveillance. Second, the Pennsylvania Supreme Court's concerns about the degree of certainty required can easily be accommodated by requiring that a jury be able reasonably to determine that medical monitoring is probably, not just possibly, necessary.

916 F.2d at 850-51; *see also Mauro v. Raymark Industries,* 561 A.2d 257, 263 (N.J. 1989) (rejecting plaintiff's claim for damages based on an enhanced risk of cancer but allowing a claim for medical monitoring); *cf. Meyerhoff v. Turner Constr. Co.,* Volume N.W.2d 847, (Mich. 1993) (holding that medical monitoring was a valid claim under Michigan law and did not require excessive speculation as to the level of damages). Thus, the Pennsylvania Superior Court decisions since *Paoli I* are not the "clear statement" or "persuasive evidence of a change in Pennsylvania law," we have required in order to depart from a prior precedent of this court. *Calgon,* 917 F.2d at 1343.

B. *The Medical Monitoring Test Restated*

In *Paoli I,* we set out the following elements as necessary to make out a medical monitoring claim:

> 1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.
>
> 2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.
>
> 3. That increased risk makes periodic diagnostic medical examinations reasonably necessary.
>
> 4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

Paoli I, 916 F.2d at 852. We stated that, "the appropriate inquiry is not whether it is reasonably probable that

plaintiffs will suffer harm in the future but rather whether medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease." *Id.* at 851. But we cautioned that a jury must "be able reasonably to determine that medical monitoring is probably, not just possibly necessary." *Id.* at 851.

Since our decision in *Paoli I*, some courts that have allowed medical monitoring claims have imposed threshold requirements that a plaintiff must meet to show that a chemical has significantly increased his or her risk of disease, and defendants argue that we should follow these courts. But we have no basis for predicting that Pennsylvania would adopt these threshold requirements. In *Theer v. Philip Carey Co.*, 628 A.2d 724, 733 (N.J. 1993), the New Jersey Supreme Court made clear that the medical monitoring cause of action it originally set forth in *Ayers v. Jackson*, 525 A.2d 287 (N.J. 1987), is not "easily invoked" and that it can only be invoked by plaintiffs "who have . . . experienced direct and hence discrete exposure to a toxic substance and who have . . . suffered an injury or condition resulting from that exposure and whose risk of cancer [can] be limited and related specifically and tangibly to that exposure." Thus, a plaintiff who was exposed to asbestos by laundering her husband's clothes had no viable medical monitoring claim—it was too difficult to quantify her exposure or to separate any potential risk from that caused by her smoking. *See id.*

We are not certain as to the import of *Theer*. It may not apply to plaintiffs who have PCBs in their own soil. At all events, we have no persuasive evidence that Pennsylvania would adopt New Jersey's rule. *See Calgon*, 917 F.2d at 1343. Someone indirectly exposed to one chemical might have as much risk of disease as someone directly exposed to another chemical, and yet New Jersey's rule would allow only the person directly injured to bring a medical monitoring claim.

Defendants also cite *Abuan v. General Electric Co.*, 3 F.3d 329, 334 (9th Cir. 1993), in which the Ninth Circuit concluded that statements by experts that a group of plaintiffs had a significantly increased risk of cancer as a result of exposure to PCBs was insufficient under the *Paoli I* standard for medical monitoring. The court explained that, "[n]either expert . . . attempted to state how 'significant' or relative the increased risk was for any individual, either in the abstract or as compared to other members of the class. Thus, their evidence failed to meet the *Paoli* significance standard." *Id.* But where experts individualize their testimony to a group of individuals with a common characteristic (*i.e.*, levels of exposure to chemical X above Y amount), we do not think there is a need for greater individualization so long as they testify that the risk to each member of the group is significant. We fail to see the purpose in requiring greater individualization. Nor do we think that an expert must quantify the increased risk. *See Ayers,* 525 A.2d 287 (N.J. 1987) (holding that where medical experts testified that a group of 300 plaintiffs who had drunk contaminated well water were subject to a significant but unquantifiable increased risk of cancer, the plaintiffs had made out a medical monitoring claim).

We are not overly concerned about the possibility of a flood of litigation absent a per se rule requiring direct exposure, actual injury, and testimony about an individual's particular level of exposure, because a plaintiff is not likely to desire to submit to additional medical tests unless he or she thinks the tests are really needed. And the damages available in a medical monitoring claim—the cost of the tests—are not likely to be high enough to provoke a flood of litigation. We predict that Pennsylvania would not want to make the cost of bringing a medical monitoring claim so high (by requiring extensive study of the particular plaintiff) that it would never be worthwhile to bring such a claim.

Nonetheless, as is apparent from the test we set forth in *Paoli I*, we think that Pennsylvania would set some limits on medical monitoring claims. And we think that the Utah Supreme Court test has encapsulated the limits we set forth in *Paoli I*. In order for a plaintiff to show significant exposure that causes a significantly increased risk to plaintiff of contracting a serious disease that makes periodic testing reasonably necessary, we think that a plaintiff must:

> prove that by reason of the exposure to the toxic substance caused by the defendant's negligence, a reasonable physician would prescribe for her or him a monitoring regime different than the one that would have been prescribed in the absence of that particular exposure. This is because under this cause of action, a plaintiff may recover only if the defendant's wrongful acts increased the plaintiff's incremental risk of incurring the harm produced by the toxic substance enough to warrant a change in the medical monitoring that otherwise would be prescribed for that plaintiff.

Hansen v. CCI Mechanical, Inc., 858 P.2d 970, 980 (Utah 1993).[53]

The court continued:

> [I]f a reasonable physician would not prescribe it for a particular plaintiff because the benefits of the monitoring would be outweighed by the costs, which may include, among other things, the burdensome frequency of the monitoring procedure, its excessive price, or its risk of harm to the patient, then recovery would not be allowed.

Id.

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[53] If there are alternative causes of a plaintiff's need for medical monitoring, Pennsylvania tort law requires that a plaintiff demonstrate that defendant's actions were a substantial factor in the plaintiff's need for medical monitoring.

C. *Application of the Test*

In order to assess whether the plaintiffs presented sufficient evidence to survive summary judgment on their medical monitoring claims, we must first determine whether the district court's decisions to exclude some of the plaintiffs' evidence was proper. We then discuss whether, given the admissible evidence, the plaintiffs satisfied their burden to avoid summary judgment on the medical monitoring cause of action we outlined above.

1. Admissibility of plaintiffs' evidence

a. Dr. Sherman's Testimony

The district court excluded Dr. Sherman's testimony regarding medical monitoring along with the rest of her testimony. The district court held that because Dr. Sherman testified that she did not know what the terms "specificity" or "sensitivity" of a medical test referred to, her methodology in ordering medical monitoring tests was unreliable. Defendants' expert Dr. Roediger explained the meaning of the terms specificity and sensitivity. He stated that if a medical test were designed to ascertain whether a person had a particular illness, a more specific test would produce an affirmative result only when it was quite certain that the person had the illness; while a more "sensitive" test would produce an affirmative result even if there was only a remote chance that the person had the illness.

Dr. Roediger also testified that "it is a necessity to understand the concept because as this antibody assay laboratory material was referred to, one has to be aware of sensitivity and specificity in order to place any relationship to the relevance of that to the case." He also testified that one could not do original research without understanding these concepts. Dr. Weitekamp added that, "I don't think you can apply a test to clinical practice, unless you have an understanding of sensitivity and specific-

ity." Based on this testimony, the district court excluded Dr. Sherman's testimony and, because only Dr. Sherman proposed a particular medical monitoring program for the Kohn/Klehr plaintiffs, granted summary judgment against these plaintiffs on their medical monitoring claims.

Although the district court's holding is facially based on methodology, its rationale seems to be based more on Dr. Sherman's expertise, i.e., the court seems to be holding that no one who fails to understand the concepts of sensitivity and specificity is qualified to testify as to what diagnostic techniques are appropriate for a particular patient. While a court can appropriately take into account an expert's degree of expertise in conducting its *Daubert* analysis, *see supra* at 40-43, it cannot exclude the expert's opinion based solely on a supposed lack of expertise when the expert meets the qualifications of Rule 702. The danger in what the district court has done here is that it has circumvented Rule 702's liberal standards of qualifications for experts by a strict reading of the requirement of a reliable methodology.

We have already held that Dr. Sherman is qualified to give expert testimony as an internist—an expertise that inherently involves decisions as to what diagnostic techniques are appropriate. We do not think that her inability to identify the meaning of two technical terms eradicates that expertise—especially where there was no exploration of the question whether Dr. Sherman's failure to recognize the two terms also demonstrated a failure to understand the substantive concepts those terms represented. Moreover, Dr. Roediger's testimony that an understanding of these terms was important took place in the context of his analysis of Dr. Sherman's ability to interpret the immunological tests—not in the context of analyzing Dr. Sherman's ability to determine what tests should be performed generally (such as for medical monitoring). And Dr. Weitekamp's testimony that one cannot "apply a test to clinical practice," absent an understanding of these terms,

seems only to mean that one cannot interpret certain tests without understanding these terms—it does not seem to mean that one cannot know what tests are appropriate without understanding the terms.

It may be true that failure to analyze the specificity or sensitivity of a particular test sometimes constitutes a methodological flaw that renders a doctor's opinion that that test is a useful diagnostic technique unreliable and hence inadmissible. But the defendants fail to point to evidence in the record suggesting that an analysis of specificity and sensitivity is necessary for the diagnostic tests Dr. Sherman prescribed for these plaintiffs to undergo, or to evidence that Dr. Sherman failed to analyze specificity and sensitivity in substance, although she did not understand the particular terms.

There may be other flaws in Dr. Sherman's methodology for concluding that particular tests are needed which, when considered in light of Dr. Sherman's limited expertise, render her opinion as to the need for a particular test inadmissible. It may be that in order reliably to evaluate the need for a particular type of test, one has to read the medical literature on the value of that test. Dr. Sherman did not always read such literature. For example, she suggested that plaintiffs should have a dental exam to check for any malignancies in the mouth or throat—especially lymphomas, but her view that dental exams were effective in detecting lymphomas was based on one friend of hers whose lymphoma had been detected in such an exam, and her view that early detection could help cure lymphoma was based on her diagnosis of 10-50 patients, none of whom she treated herself.[54]

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[54] Other potential problems existed as well. Dr. Sherman stated that the plaintiffs should undergo a chromosomal analysis to look for evidence of leukemia but admitted that she had not made any evaluation of the predictive value of such an analysis, although she stated that there was some literature advocating such a use of the tests. (JA 843-44). She recommended performance of an

Yet defendants do not make these arguments; nor do they point to any evidence that a doctor cannot reliably evaluate the worth of particular medical tests based on anecdotal evidence gathered over a lifetime of involvement in the medical profession; nor did the district court base its decision on this basis. Thus, we hold that the district court abused its discretion in relying purely on Dr. Sherman's failure to understand certain terms in excluding her testimony on medical monitoring as unreliable.

b. Dr. DiGregorio's testimony.

i. Reliability

Dr. DiGregorio testified that, as a result of their exposure to PCBs, the Hanes plaintiffs had a greater risk of contracting future illnesses than average members of the population. He stated that this would be true of anyone exposed to even one molecule of PCBs, and that, as a result, plaintiffs should undergo medical monitoring.

The court excluded Dr. DiGregorio's testimony under Rule 702 finding that his methodology was "non-existent, and therefore completely unreliable." In the court's view, Dr. DiGregorio's statement that he needed to examine plaintiffs before he could render a final opinion as to the cause of their present illnesses, combined with his reliance on plaintiffs' statements for evidence of their PCB exposure rather than conducting independent tests of the amount and source of plaintiffs' PCB exposure, made his conclusion that they needed medical monitoring unhelpful in showing "to a reasonable degree of medical certainty": (1) that medical monitoring is "necessary in order to diagnose properly the warning signs of disease," (2) that plaintiffs were significantly exposed to a hazardous substance, or (3) that the exposure came from the

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alpha globulin test although she did not know how such a test was performed today and had not performed such a test since 1968 or 1969.

railyard, quoting *Paoli I* 916 F.2d at 851 (quoting *Askey v. Occidental Chemical Corp.*, 477 N.Y.S.2d 242, 247 (1984) (internal quotation marks omitted)). The district court also noted that Dr. DiGregorio was unable to state an opinion on whether any plaintiffs would develop future injuries, and could not quantify the increased risk they faced.[55]

Plaintiffs respond that Dr. DiGregorio did not need to examine the patients to determine that they were exposed to significant *future* risk of developing disease. Plaintiffs cite the "Proposed Plan Paoli Railyard Superfund Site" authored by the EPA in March of 1992 which found extensive PCBs in residential soil and an "incremental cancer risk for children and adults in the residential area near the Rail Yard with lifetime exposure to residential soils . . . in the range of 1×10^{-4} to 1×10^{-5}." Plaintiffs note that they lived for many years directly adjacent to the railyard and were significantly exposed to soil from their yards and the railyard. Given such a risk, they contend, Dr. DiGregorio employed perfectly acceptable methodology in concluding that "medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease." The fact that Dr. DiGregorio would not say with a reasonable degree of medical certainty that plaintiffs *would* become ill in the future and would not quantify plaintiffs' increased risk is, in their view, irrelevant. He was willing to say with a reasonable degree of medical certainty that they needed medical monitoring.

We agree with plaintiffs that Dr. DiGregorio could reliably testify as to a patient's future risks without ex-

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[55] In addition to his testimony about present illnesses and medical monitoring, Dr. DiGregorio also testified to some general evidence that PCB caused harm in humans and in animals (JA 2634-35, JA 2655) and for the reasons about his confidence in extrapolating from animal studies for PCBs (JA 2655). It is not clear on what basis the district court excluded this testimony and it appears to be admissible.

amining the patients. None of the defendants' experts stated that physicial examinations were necessary in order to reliably predict future risks; they were all testifying about the methodology necessary in order to evaluate present illnesses. We also agree that a doctor does not have to testify that a plaintiff will become ill in the future in order to justify medical monitoring. Finally, we agree with the plaintiffs that Dr. DiGregorio had sufficient data to conclude reliably that the plaintiffs had been significantly exposed to PCBs. In 1988, Dr. DiGregorio reported that he based his assessment of exposure on a residential history of each plaintiff, and on fat and blood tests of the various plaintiffs which he had performed.[56] Defendants did not present any evidence that these types of data are unreliable or that it is an unreliable methodology to use this data to assess exposure for the purpose of determining the need for medical monitoring.

ii. Failure to Comply With the Scheduling Order

In addition to testifying that the Hanes plaintiff should receive medical monitoring, Dr. DiGregorio submitted a medical monitoring program that he thought the plaintiffs should undergo. The district court precluded him from testifying regarding this program because he was late in producing it. The plaintiffs challenge this ruling.

On June 4, 1991 the court ordered plaintiffs to file their Rule 26(b)(4) statements detailing the substance of their experts' testimony by March 17, 1992. *See supra* pp. 36-37. However, as of Dr. DiGregorio's April 16, 1992 deposition, in which he asserted that the plaintiffs should be subject to a medical monitoring program, the plaintiffs

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[56] While in his 1992 deposition, Dr. DiGregorio testified that it may well have been that his source of evidence of plaintiffs' exposure was their own testimony, he also stated he had not reviewed his records and that he had previously stated his source (in 1988). The 1988 statement is part of this record.

had not submitted any medical monitoring program prepared by Dr. DiGregorio to the court. In fact, at the time of his deposition, Dr. DiGregorio had still not developed such a program and did not do so until two days later (April 18). As a result, the district court excluded Dr. DiGregorio's opinion about medical monitoring. As the district court explained, it had the authority under Rule 37(b)(2)(B) of the Federal Rules of Civil Procedure to sanction a party's failure to comply with a discovery order by "prohibiting that party from introducing designated matters in evidence." Fed. R. Civ. Pro. 37(b). "The trial court's exclusion of testimony because of the failure of counsel to adhere to a pretrial order will not be disturbed on appeal absent a clear abuse of discretion." *Semper v. Santos*, 845 F.2d 1233, 1237 (3d Cir. 1988). In evaluating whether the district court properly exercised its discretion, we consider:

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order.

Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894 (3d Cir. 1977). "[T]he exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Id.* at 905 (quoting *Dudley v. South Jersey Metal, Inc.*, 555 F.2d 96, 99) (3d Cir. 1977).

Applying the *Pennypack* factors, the district court found that, although the plaintiffs' had identified Dr. DiGregorio as a witness by the March 17 deadline and although Dr. DiGregorio had previously testified that plaintiffs needed a medical monitoring program, the plaintiffs' failure to

identify the substance of that program by the deadline prejudiced the defendants. Development of the specifics of the program on April 18 left the defendants only 60 days before the deadline the court had set for deposition of experts to depose Dr. DiGregorio about the program and to find new experts to examine the plaintiffs and come up with their own proposal for monitoring. Most important, the court's finding that plaintiffs' delay in submitting a medical monitoring program was due to bad faith and willfulness, and that was because the plaintiffs had failed to complete in nine and a half months a task that turned out only to take two days.

We have great difficulty with the district court's rulings. The prejudice to the defendants here is extremely minimal. Plaintiffs properly identified Dr. DiGregorio as a witness by the March 17 deadline, thus the defendants knew that he was going to testify. They were also aware of the general substance of his testimony and even some of the specifics of his plan for medical monitoring. In his April 4, 1988, deposition, Dr. DiGregorio stated that he would:

> do a base line Physical and history . . . . I would include a serum PCB level, a possible fat biopsy for PCB's. And then depending on the results and what type of information we get back from them, I would make my evaluation at that point. That would be my baseline program.

Moreover, defendants were provided with all of the specifics of Dr. DiGregorio's proposed medical monitoring plan on April 18, only a month after the district court's deadline, four months before the schedule trial date, and 60 days before the deadline the district court had set for ending discovery. Thus, the defendants had abundant time to depose Dr. DiGregorio regarding the specifics of his proposed program before the discovery deadline, and the district court could easily have extended the deadline to provide the defendants even more time. As a result, under the first three *Pennypack* factors—1) prejudice to the

defendant 2) ability to cure the prejudice and 3) degree of disruption of an orderly trial or of other cases, there is little in favor of exclusion.

Although we have generally upheld trial courts' imposition of sanctions excluding witnesses because of the district court's need for broad leeway to manage its cases, *see, e.g., United States v. 68.94 Acres of Land*, 618 F.2d 389, 396-97 (3d Cir. 1990); *Semper v. Santos*, 845 F.2d 1233, 1237-38 (3d Cir. 1988), *Coleco Industries Inc. v. Berman*, 567 F.2d 569-70 & n. 14 (3d Cir. 1977), we have reversed an exclusion where, as is the case here, there was only a slight deviation from pre-trial notice requirements, and admitting the witness was likely to cause only slight prejudice to the defendants, who were already aware of the basic substance of the witness' testimony. *See De Marines v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1202 (3d Cir. 1978). In fact, admission of the testimony in *KLM* was far more likely to cause prejudice than it was here, because the defendant in that case did not make the plaintiffs aware of the exact substance of the testimony until *trial*. Similarly, in *Pennypack*, we reversed the district court's exclusion of expert testimony despite the fact that the substance of the testimony was revealed far closer to trial than it was here (three weeks before trial), and where there was the possibility of some disruption of the trial or of other cases through the need to give the defendant an opportunity to depose the new witnesses. *See Pennypack*, 559 F.2d at 905.

The main possible justification for the district court's decision is that, unlike the courts in *KLM and Pennypack*, the district court made an explicit finding that the plaintiffs' failure to provide the specifics of Dr. DiGregorio's medical monitoring program was a result of bad faith. The court found:

> Plaintiffs were given nine and one-half months to develop a monitoring program. The Plaintiffs' attorneys merely had to ask Dr. DiGregorio to proceed

> with the development of this program, and it is shown that two days later a completed program would be in their hands. . . . Their lack of diligence in this matter constitutes a willful failure to comply with the Court's order.

But the district court's finding of willfulness and bad faith is clearly erroneous. Where plaintiffs named Dr. DiGregorio by the deadline, provided most of the substance of his testimony by the deadline, provided the additional substance shortly after the deadline when requested to do so, and had little to gain from the month delay in provision of the additional material, there is no basis on which to conclude that the plaintiffs deliberately failed to comply with the requirements of the district court order. "Lack of diligence" does not constitute bad faith.

Thus, in excluding Dr. DiGregorio's specific proposals for medical monitoring, the district court abused its discretion. As in *Pennypack*, the district court could have imposed a lesser sanction such as providing the defendants with the opportunity to re-depose Dr. DiGregorio and taxing the costs to the plaintiffs. *See Pennypack*, 559 F.2d at 905.

c. Dr. Schecter's testimony

Dr. Arnold Schecter, M.D., testified regarding laboratory blood tests and fat samples showing PCB levels above background for each plaintiff. However, the Hanes plaintiffs specifically told the district court that Dr. Schecter was not going to testify as to exposure or increased risk, but only that the plaintiffs increased fear of disease was reasonable. Thus, the court did not consider Dr. Schecter's testimony in analyzing plaintiffs' medical monitoring evidence on summary judgment. We hold that the district court was perfectly justified in determining that Dr. Schecter's testimony was not relevant for summary judgment purposes on any of plaintiffs' claims because plaintiffs' claims based on fear of disease are not cognizable under Pennsylvania law, *see supra* 128 & n. 51, and this was the only issue on which Dr. Schecter was supposed

to testify. We turn now to whether the plaintiffs have enough admissible evidence to avoid summary judgment on medical monitoring.

2. Summary judgment on medical monitoring

Five of the Kohn/Klehr plaintiffs (Bessie Cunningham, Matthew Cunningham, Amber Burrell, Priscilla Burrell and Patricia Ingram) presented the testimony of Dr. Nisbet to prove their significant exposure to PCBs. They, along with the rest of the Kohn/Klehr plaintiffs, also relied on soil samples in their yards showing PCB levels to be significantly above those deemed acceptable by the EPA. For example, levels in the Burrell's yard were measured in 1986 as high as 21 ppm, in Monica Hilton's yard as high as 21 ppm, in the Cunningham's yard as high as 7,000 ppm with 10 of 14 samples more than 60 ppm.[57]

The Hanes plaintiffs intended to rely partly on their own testimony as evidence of exposure—they planned to testify that they played in the Yard, that they lived near the Yard, and engaged in many activities on the soil in their yards. They did not point to any evidence documenting the levels of PCBs in their soil, but did point to EPA's general conclusion in its "Proposed Plan Paoli Railyard Superfund Site," which states that the Yard and nearby residential soils and streams were contaminated with PCBs. Moreover, Dr. DiGregorio testified regarding

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[57] In their supplemental submission, plaintiffs did not cite evidence regarding the soil level of PCBs at the homes of those plaintiffs who sought medical monitoring damages but did not seek damages for present injuries. These plaintiffs were Theresa Butler, William Butler, Marvin Simpson, Donald Simpson, Karen Simpson, Alan Simpson and Brian Jackson. Moreover, the levels of PCBs in the soil of Mabel Brown were 1.6 ppm—within the range EPA deems acceptable. But the defendants did not point to an absence of evidence of PCBs in the soil as a reason to grant summary judgment with respect to any of these plaintiffs, and thus, plaintiffs were under no obligation to point to it in response to the summary judgment motion or to place such evidence in the appellate record.

laboratory blood tests and fat samples showing PCB levels for each plaintiff, levels he thought were quite significant. We note that this evidence acquires added significance in light of Dr. Nisbet's admissible testimony that background levels are much lower than defendants contend.

All plaintiffs presented evidence that their exposure was significant enough to cause them a significantly increased risk of contracting disease. In EPA's Risk Assessment for the Paoli PCB Superfund site, it concluded that PCB levels in residential soils must be reduced to two parts per million to reduce cancer risks to acceptable levels (EPA has set acceptable risk at 1 in 100,000, although EPA's point of departure for risk assessments is 1 in 1,000,000). As was mentioned above, EPA's March 1992 "Proposed Plan Paoli Railyard Superfund Site" concludes that there are presently extensive PCBs in residential soils in Paoli which create an "incremental cancer risk for children and adults in the residential area near the Rail Yard with lifetime exposure to residential soils . . . in the range of 1×10^{-4} to 1×10^{-5}. Some plaintiffs presented additional evidence that they were subject to a significant risk of future serious disease. Dr. Nisbet testified that Priscilla Burrell had been exposed to sufficient levels of PCBs to cause adverse health effects, and that the Cunninghams had been "sufficiently exposed to PCBs to give rise to the expectation that they would suffer adverse health effects." With respect to Matthew Cunningham this was based on the fact that he had burned firewood and leaves from his yard and breathed the fumes and had eaten vegetables from his yard. Dr. Nisbet concluded that Amber Burrell's exposure was sufficient to cause serious health conditions, and that Patricia Ingram's exposure was sufficient to expect an effect on her immune system.

The fact that the risks to individuals in the Paoli area were high enough to warrant cleanup action by the EPA does not necessarily mean that they were high enough to

warrant medical monitoring.[58] But plaintiffs presented evidence that the risks from PCB exposure were significant enough to justify the costs of medical monitoring. Dr. Sherman testified that all of the plaintiffs should receive medical monitoring. She stated that anyone who lived near a toxic dump site, even if they had PCBs in their blood at levels as low as one part per billion, and even if they lived three blocks away from the site, should receive medical monitoring. Because all of the plaintiffs, including the Hanes plaintiffs, live near a toxic dump site, Dr. Sherman's testimony applies to them as well. Similarly, Dr. DiGregorio testified that all of the plaintiffs were at:

> risk because of their exposure to PCBs, some of which will be sensitive enough to be involved with one molecule . . . . So, a good physician or good scientist will set up a medical monitoring program to look at that. That's what the basis for a medical monitoring program is, to look for those people that are sensitive.[59]

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[58] Conversely, medical monitoring may sometimes be justified even though EPA concludes that remaining risks are acceptable given the costs of cleanup.

[59] Dr. DiGregorio's testimony that exposure to one molecule of PCBs warrants medical monitoring might imply that everyone should recieve medical monitoring because everyone in the population has probably been exposed to one molecule through backbround levels of PCBs. But this approach would not allow a reasonable jury to conclude that plaintiffs should receive such monitoring as a result of exposure to *defendants'* PCBs. Moreover, a conclusion that everyone who has been exposed to even one molecule of PCBs should receive medical monitoring evidences giving little consideration to the cost of the monitoring. Similarly, Dr. Sherman's testimony that everyone who lives near a toxic dump site should be subject to medical monitoring gives little evidence that she took into account the cost of medical monitoring. These aspects of plaintiffs' medical monitoring claims are somewhat underwhelming. But defendants did not ask Drs. Sherman and DiGregorio why they thought the risk to plaintiffs was high enough to justify the cost of medical monitoring; nor did they ask Dr. DiGregorio what made

This testimony also applies to each of the plaintiffs because they all had exposure to more than one molecule of PCBs.

The plaintiffs also presented evidence of diagnostic techniques that would make the "early detection and treatment of the disease[s] possible and beneficial." *Paoli I*, 916 F.2d at 852. Dr. Sherman prepared a sample protocol of diagnostic techniques she though would benefit plaintiffs. Dr. Sherman's protocol applies to the Hanes plaintiffs as well, because she thought that her protocol was applicable to everyone exposed to PCBs from the Paoli railyard. Moreover, Dr. DiGregorio presented a medical monitoring plan that we have held is admissible. *See supra* 142.

The opinions of Drs. DiGregorio and Sherman with respect to the medical monitoring issues pass *Daubert* muster. Moreover, on the present record, they survive summary judgment. Whether or not they will carry the day before a jury is quite another matter. Certainly the EPA risk assessement for the Paoli PCB Superfund Site is important and will be of aid to plaintiffs. On the other hand, the jury may or may not find the opinions of Drs. Sherman and DiGregorio sufficient to meet the *Paoli I* standard (with the Utah gloss thereon), *see supra* pp. 129-134. For now, we simply note that, given the admissibility of the DiGregorio and Sherman opinions on medical monitoring, which were not seriously challenged during the *in limine* hearing, the medical monitoring claims do survive summary judgment.

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him conclude that it was exposure to defendants' PCBs that justified medical monitoring. Thus, defendants failed to point to anything in the record that would prevent the issue of medical monitoring from going to a jury. The opinions of Drs. Sherman and DiGregorio thus created a genuine issue of material fact as to whether defendants' PCBs created a risk to plaintiffs significant enough to justify the cost of medical monitoring.

XII. PROPERTY DAMAGE

In addition to suing for personal injuries and medical monitoring, nine plaintiffs [60] sued for the diminution in property value of their homes caused by the proximity of the Yard and the presence of PCBs on their land. The district court granted summary judgment for the defendants on this claim.

The district court found that the EPA already has a plan under which it can and will remove the alleged contamination to plaintiffs' property. The court found that the plaintiffs had not submitted any evidence to indicate that EPA's remedy would not be effectuated or would be inadequate with regard to real property or groundwater contamination. The court concluded that absent *permanent* physical damage, plaintiffs had no claim. Any decrease in market value caused by the stigma associated with living near the railyard was not, in its view, compensable under Pennsylvania law. The court held that harm to the property (repair costs) rather than diminution of value is the proper measure of damages where the harm is temporary and remediable (citing *Kirkbride v. Lisbon Contractors*, 560 A.2d 809, 812 (Pa. Super. (1989)); and *Rabe v. Shoenberger Coal Co.*, 62 A. 854 (Pa. 1906)). The court stated that only if the damages are permanent is the proper measure of damages the diminution in value (citing *Ridgeway Court, Inc. v. Landon Courts, Inc.*, 442 A.2d 246, 248 (Pa. Super. 1981), and that Pennsylvania law presumes that damage is temporary and remediable and justifies a finding to the contrary only if the harm is "unequivocally beyond repair." (citing *Kirkbride*, 560 A.2d at 812-13). Here, according to the district court, the damage to the property was repairable.

---

[60] Mabel Brown, K. Louise Jones, James Lament, Christopher Brown, Margherita Barbetta, Mary Retta Johnson, John Ingram, William Butler, and Matthew Cunningham.

Plaintiffs respond that even under the rule cited by the district court, the proper measure of damages is diminution in market value because there was in fact permanent damage to plaintiffs' property. First, EPA itself estimates that its cleanup will lower cancer risk only to 1 in 100,000, which is ten times higher than its normal remedial goal of lowering risk to 1 in 1,000,000. Second, Dr. Kopstein indicated that the EPA plan will not be effective in eliminating groundwater contamination, exposure through the air, and the continuing release of sediments from the Yard.

However, the district court found that Dr. Kopstein did not assert that a human health hazard would remain. He only stated that he could not calculate the levels of exposure levels from groundwater, air and sediment runoffs that would remain after the cleanup. The court added that Dr. Kopstein's testimony had only been offered for the purpose of establishing plaintiffs' "opportunities for exposure" to PCBs and thus could not establish a continuing health hazard. It noted that EPA's reduction of PCB levels to 2 ppm ensures that these levels are less than those the FDA allows in food packaging material, poultry and animal feed. *See* 21 C.F.R. § 109.30.

Despite Pennsylvania's presumption that damage is not permanent, we think the district court's decision to grant summary judgment was incorrect. As we see it, the EPA's own normal practice of cleaning up property to the point where the risk is 1 in 1,000,000 creates a genuine issue of material fact as to whether a cancer risk of 1 in 100,000 constitutes permanent damage; the tension with the FDA standards is for the jury to resolve. Moreover, the clear import of Dr. Kopstein's testimony, giving every inference to the nonmoving party, is that a human health hazard will remain after the EPA cleanup. In testifying to "opportunities for exposure," Dr. Kopstein could certainly testify that exposure on plaintiffs' properties was likely to continue to be high.

Plaintiffs also presented evidence to demonstrate permanent damage in a second way. While the requirement of permanent damage *to property* seems on its face to require permanent physical damage, plaintiffs convincingly argue that the stigma associated with the prior presence of PCBs on their land constitutes permanent, irremediable damage to property under Pennsylvania case law such that they can recover for the diminution of value of their land. They cite *Willsey v. Kansas City Power & Light Co.*, 631 P.2d 268, 273-75 (Kan. App. 1981), which states that in eleven of twenty six jurisdictions to consider the issue, loss of market value is recoverable when the government takes part of an owner's property and places electric power lines on it even if the market's fear of the power lines is unreasonable, *see e.g., United States ex rel Tennessee Valley Authority v. Easement and Right of Way*, 405 F.2d 305, 309 (6th Cir. 1968) ("[I]n final analysis, we are only concerned with market value. Although these studies may show objectively the complete safety of these structures, we are not convinced that certain segments of the buying public may not remain apprehensive of these high voltage lines"), and that in another nine jurisdictions, the rule is that diminution of market value is compensable so long as it has some reasonable basis, *see, e.g., Kentucky Hydro Electric Co. v. Woodard*, 287 S.W. 985 (Ky. 1926) ("If he cannot sell his property at as good a figure with this line on it as he could without it by reason of reasonable fears, not speculative but founded on experience and entertained by those who wish to buy, has he not been damaged in this regard?").

Plaintiffs submit that Pennsylvania has essentially adopted one of these two positions and that it applies to tort cases as well as takings cases. In *Appeal of Giesler*, 622 A.2d 408, 411-12 (Pa. Commw. 1993), decided after the district court decision in this case, the court held in a takings case that just compensation for land taken by the government to run an electric power line included full diminution of market value of the remaining land. The court quoted *United States v. Easement and Right-to-Way*,

249 F.Supp. 747, 750 (W.D. Ky. 1965) which held that, "[a]pprehension of injuries to person or property by the presence of power lines on the property may be taken into consideration insofar as the line affects the market value of the land. In the opinion of the Court, the apprehension of such danger constitutes an element of damage." 622 A.2d at 411-12. The court made this determination even though evidence on the health effects of electric lines was speculative.

Wade v. S.J. Groves & Sons Co., 424 A.2d 902, 912 (Pa. Super. 1981), also supports the proposition that a reduction in market value is recoverable even absent permanent physical damage to the plaintiffs' property. *Wade* involved the negligent modification by plaintiff's neighbor of a natural gully on that neighbor's land which changed the drainage patterns on that land and caused flooding on plaintiffs' land. The damage was repairable and the Wades were able to reduce to negligible levels any significant risk of future damage by undertaking a variety of flood control measures. *See id.* at 911. Nonetheless, there was a permanent change in the flood plain of the neighbor's land, a slight ongoing risk of renewed flooding, and a significant diminution in the value of the Wades' land. Despite the fact that the actual permanent change was to the neighbor's land, the court allowed compensation for the diminution in market value to the plaintiff's property that would remain after repairs were made. *See id.* at 911-12.

Defendants assert that *Wade* and *Giesler* do not support plaintiffs' proposition, and that plaintiffs' citation to the law of other jurisdictions is irrelevant and contradicted by the law of other jurisdictions. *See, e.g., Adams v. Star Enterprise*, 1994 WL 172266 at * 3 (E.D. Va. 1994) (holding that stigma damages based on unfounded fear about dangers in the vicinity of property are unavailable in a nuisance action). Defendants submit that the presence of the electric lines in *Giesler* and the change in the flood plain in *Wade* were permanent

whereas the PCBs here are, presumably, not present permanently. However, the permanent physical changes in *Wade* and *Giesler* were to neighboring land; there was no permanent physical change to plaintiffs' land. Defendants respond that the changes to neighboring land posed a continuing risk of damage to plaintiffs' land. But it is not clear why this continuing risk constitutes permanent physical damage to any greater extent than the continuing stigma of living on property which once contained significant amounts of PCBs.

Moreover, defendants are incorrect that the changes to neighboring land in *Giesler* posed a continuing risk to plaintiffs' land. The *Giesler* court assumed that the electric lines caused no actual physical risk of any sort to plaintiffs' land. This means that the only ongoing damage to the property in *Giesler* was the diminution in value caused by the stigma of living near electric lines which is comparable to the stigma of living on property which once contained significant quantities of PCBs.[61] And, in any case, there is *some* ongoing risk to plaintiffs here based on the admittedly small quantities of PCBs left on the land.[62]

---

[61] It is possible to argue that the *taking* of property to install the electric lines in *Giesler* was permanent—thus, there *was* a permanent change to some of the Gieslers' land. However, the Gieslers could have been fully compensated for the permanent loss of *this* land without being compensated for the diminution in value of their remaining land—land which was not physically damaged. Moreover, in *Wade*, there was no taking of plaintiffs' land nor any permanent damage to plaintiffs' land.

[62] Defendants also attempt to distinguish *Giesler* on the basis that it was a takings case not a tort case. However, *In re Larsen*, 616 A.2d 529 (Pa. 1992), *cert. denied*, 114 S. Ct. 65 (1993), held that compensation in a tort case is generally at least as great as in a takings case. In a tort case, unlike a takings case, the goal is to compensate the plaintiff "for all injuries proximately caused by the defendant's action" including property lost and incidental injuries not recognized in eminent domain actions. *See Larsen*, 616 A.2d at 599-600. Indeed, *Wade* was a tort case.

Even if the facts of *Wade* and *Giesler* are somewhat distinguishable from the facts here, the principles articulated in *Wade* essentially eliminate the possibility that an injury to land must be physical for it to be considered permanent. After citing the traditional Pennsylvania rule that diminution in market value is only recoverable if damage is permanent, the court stated that the term permanent injury was meant to apply whenever repair costs would, for some reason, be an inappropriate measure of damages. *See Wade,* 424 A.2d at 912. And an appropriate measure of damages is generally defined as what is necessary to compensate fully the plaintiff. *See id.* at 911-12.

This approach is normally consistent with the view that, when physical damage is temporary, only repair costs are recoverable, because in a perfectly functioning market, fully repaired property will return to its former value. Thus, an award of repair costs will be fully compensatory. And it makes sense to award repair costs rather than the equivalent diminution of value absent repair, because it is easier to measure repair costs. Hence, normally, it is only when property cannot be repaired that courts must award damages for diminution of value in order to fully compensate plaintiffs. However, the market sometimes fails and repair costs are not fully compensatory. In such cases, according to the principles of the *Wade* court, plaintiffs should be compensated for their remaining loss. Absent such an approach, plaintiffs are permanently deprived of significant value without any compensation. *See id.*

Although post-*Wade* cases, including Pennsylvania Supreme Court cases, continue to cite the traditional Pennsylvania rule without discussing *Wade*'s interpretation of that rule, *see, e.g., Kirkbride,* 560 A.2d at 813 (holding that "where an injury is reparable, the damage is the cost of repair or restoration") (citing *Lobozzo v. Adam Eidemiller, Inc.*, 263 A.2d 432 (1970)), none have rejected

Wade's interpertation of that rule.[63] We hope that the Pennsylvania courts will provide further guidance on this issue. For now, although *Wade* and *Giesler* are not decisions of the Pennsylvania Supreme Court, they are well reasoned decisions, and we think that at least where (1) defendants have caused some (temporary), physical damage to plaintiffs' property; (2) plaintiffs demonstrate that repair of this damage will not restore the value of the property to its prior level; and (3) plaintiffs show that there is some ongoing risk to their land, plaintiffs can make out a claim for diminution of value of their property without showing permanent physical damage to the land.[64]

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[63] Defendants' citations to the contrary are inapposite. *Hughes v. Emerald Mines Corp.*, 450 A.2d 1, 8 (Pa. Super. 1982) reversed an award of loss-in-market-value damages for the pollution of the plaintiffs' wells because restoration of those wells was possible. But the plaintiffs did not present any evidence in that case that a diminution in market value would remain even after restoration of the wells.

[64] Defendants' amicus, the American Insurance Association, cites cases from several jurisdictions where plaintiffs who lived near contaminated sites or nuclear power plants were denied recovery for diminution in property value. In *Adkins v. Thomas Solvent Co.*, 487 N.W. 2d 715 (Mich. 1992), for example, the Michigan Supreme Court held that allowing recovery in such cases might permit recovery for "unfounded fears regarding persons with AIDS moving into a neighborhood, the establishment of otherwise lawful group homes for the disabled, or unrelated persons living together, merely because the fears experienced by third parties would cause a decline in property values." *Id.* at 726. The *amicus* also argues that allowing a tort for diminution in value would allow thousands of insubstantial and peripheral claims, would often grant recoveries for routine fluctuations in market prices thus generating windfalls, and would increase insurance costs, reduce the availability of insurance, and reduce the availability of funds to compensate those who were actually injured. *See* Abraham, *Environmental Liability and the Limits of Insurance*, 88 Colum. L. Rev. 942, 972-74 (1988).

We think that these concerns are overstated. The rule we have articulated only allows recovery when there has been some initial physical damage to plaintiffs' land. *Cf. Berry v. Armstrong Rubber Co.*, 989 F.2d 822 (5th Cir. 1993), *cert. denied*, 114 S. Ct. 1067 Subnom. *Cooper v. Armstrong Rubber Co.* 1994 (holding that

Thus, we will reverse the district court's grant of summary judgment on the plaintiffs' property damage claims.

XIII. CONCLUSION

As this opinion makes clear, the Supreme Court in *Daubert* has clarified that district courts have an important role to play in policing putative experts' contributions to the truth-seeking process at trial. We are quite confident that the district court bench is equal to that task. Of course, toxic tort cases, like this one, can become staggeringly expensive undertakings for all parties involved, and often require extensive involvement by experts. Thus, we also expect that trial courts, mindful of the Supreme Court's observation that the law must "resolve disputes finally and quickly," *Daubert,* 113 S.Ct. at 2798, will continue to seek innovative ways to fulfill their duties under *Daubert* while also seeking to conserve judicial resources, as well as those of the litigants.

For the foregoing reasons the district court's grant of summary judgment on Bessie Cunningham's claims that her exposure to defendants' PCBs caused her headaches, arthritis/arthralgia and hypertension will be reversed. We will also reverse the district court's grant of summary judgment on Amber Burrell's claims that her exposure to defendants' PCBs caused her respiratory ailments. Additionally, we will reverse the district court's grant of summary judgment on the medical monitoring claims and property damage claims of all plaintiffs asserting those

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Mississippi law only allows recovery for a decrease in property value caused by stigma where there has been some physical harm to the property). This rules out recovery in cases such as the establishment of a group home for the disabled; moreover, recovery in such cases might well be barred as against public policy. Any risk of an avalanche of litigation with every market fluctuation will be prevented by the need of plaintiffs to establish causation and to prove that the stigma associated with their land will remain in place after any physical damages to their land has been repaired.

claims (they are listed in the margin).[65] However, the district court's grant of summary judgment regarding all of the other plaintiffs' claims of present injuries, and all of the plaintiffs' claims of fear of future illness and of risk of illness will be affirmed.

ROTH, *Circuit Judge, concurring*

I join in the opinion of the court except that I cannot agree with all the guidelines established by the majority in reaching their conclusion. Specifically, contrary to the majority's holding in Part V.A.4 (at pages 43 through 49) [38a-44a], I do not believe that it is "helpful" for the jury to receive information which the trial judge concludes is not accurate. In my opinion, the "gatekeeper" function of the trial judge established by the Supreme Court in *Daubert* would not be fulfilled by permitting inaccurate information to go to the jury even though the trial judge may have determined that the methodology used to produce such results is reliable.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

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[65] The following plaintiffs have asserted property damage claims: Mabel Brown, K. Louise Jones, James Lament, Christopher Brown, Margherita Barbetta, Mary Retta Johnson, John Ingram, William Butler, and Matthew Cunningham.

All plaintiffs except James Lament appear to have asserted medical monitoring claims, but the medical monitoring claims of Matthew Cunningham, who is deceased, have been extinguished.

APPENDIX II

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 92-1995

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MABEL BROWN, Individually and on behalf of all others similarly situated

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); AND
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
ROY F. WESTON, INC.; and
OH MATERIALS COMPANY; and
GENERAL ELECTRIC COMPANY; and
THE BUDD COMPANY; and
WESTINGHOUSE ELECTRIC CORPORATION;
MONSANTO CO.;
PENN CENTRAL CORPORATION
Mabel Brown, Appellant

(D.C. Civ. No. 86-02229)

No. 92-1996

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

GEORGE ALBERT BURRELL and
PRISCILLA ETHERIDGE BURRELL,
in their own right, and GEORGE ALBERT BURRELL and
PRISCILLA ETHERIDGE BURRELL, as parents and natural
guardian of AMBER SHARDAI BURRELL, a minor, and
GEORGE ALBERT BURRELL, as parent and natural
guardian of ANDRE WALKER, a minor, and
PRISCILLA ETHERIDGE BURRELL, as parent and
natural guardian of BOBBY GEORGE ALBERT
CHRISTIAN BURRELL, a minor

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION
AUTHORITY ("SEPTA"); and
NATIONAL RAILROAD PASSENGER CORPORATION
("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
MONSANTO COMPANY;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;

v.

PENN CENTRAL CORPORATION
George Burrell, Priscilla Burrell,
Amber Burrell and
Monica Hilton, Appellants

(D.C. Civ. No. 86-02235)

No. 92-1997

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

WALLACE DARRYL CUMMINS

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA"); AND
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); AND
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA; and
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
MONSANTO COMPANY
Wallace D. Cummins, Appellant

(D.C. Civ. No. 86-02669)

No. 92-1999

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

K. LOUISE JONES, ADMINISTRATRIX OF THE ESTATE OF HARVEY N. JONES, JR., DECEASED AND K. LOUISE JONES AS PERSONAL REPRESENTATIVE OF HARVEY N. JONES, JR., AND K. LOUISE JONES IN HER OWN RIGHT

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK");
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
MONSANTO COMPANY;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY; AND
WESTINGHOUSE ELECTRIC CORPORATION;
K. Louise Jones and
Harvey Jones, Appellants

(D.C. Civ. No. 86-05277)

No. 92-2000

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

JAMES LAMENT, individually and on behalf of all others similarly situated

v.

SEPTA; AMTRAK and CONRAIL;

v.

PENN CENTRAL CORPORATION;
UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
MONSANTO CO.;
GENERAL ELECTRIC CO.;
BUDD CO., AND
WESTINGHOUSE ELECTRIC CORPORATION
James Lament, Appellant

(D.C. Civ. No. 86-05886)

No. 92-2010

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

JOHN INGRAM, SR., and
PATRICIA INGRAM, in their own right and as
parents and natural guardians of JOHN INGRAM, JR.; and
APRIL INGRAM in her own right

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION
AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION
("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL"); and
MONSANTO COMPANY ("MONSANTO"); and
GENERAL ELECTRIC COMPANY ("GE"); and
CITY OF PHILADELPHIA ("PHILADELPHIA")

v.

UNITED STATES OF AMERICA;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION
John Ingram, Sr. (and as representative of decedent, Patricia Ingram), John Ingram, Jr., Patricia Ingram and April Ingram Robinson-Ray, Appellants

(D.C. Civ. No. 86-07561)

No. 92-2011

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MARY ALICE KNIGHT,
Appellant

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL"); and
MONSANTO COMPANY ("MONSANTO"); and
GENERAL ELECTRIC COMPANY ("GE"); and
CITY OF PHILADELPHIA ("PHILADELPHIA")

v.

UNITED STATES OF AMERICA;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION

(D.C. Civ. No. 87-00712)

No. 92-2014

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

WILLIAM BUTLER; THERESA BUTLER;
MARVIN L. SIMPSON; ALLEN K. SIMPSON;
KAREN R. SIMPSON; DONALD E. SIMPSON; and
BRYAN M. JACKSON

v.

SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA");
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

UNITED STATES OF AMERICA;
CITY OF PHILADELPHIA;
MONSANTO COMPANY;
GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION
William Butler, Theresa Butler, Bryan Jackson, Allen Simpson, Donald Simpson, Karen Simpson and Marvin Simpson, Appellants

(D.C. Civ. No. 87-02874)

No. 92-2016

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

MATTHEW CUNNINGHAM; AND
BESSIE CUNNINGHAM,
Appellants

v.

MONSANTO COMPANY; and
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY ("SEPTA"); and
NATIONAL RAILROAD PASSENGER CORPORATION ("AMTRAK"); and
CONSOLIDATED RAIL CORPORATION ("CONRAIL")

v.

GENERAL ELECTRIC COMPANY;
THE BUDD COMPANY;
WESTINGHOUSE ELECTRIC CORPORATION;
PENN CENTRAL CORPORATION,
Third-Party Defendants

Present: BECKER, ROTH, and LEWIS, *Circuit Judges.*

SUR PETITION FOR PANEL REHEARING

The petition for rehearing filed by Appellants, having been submitted to the judges who participated in the decision of this court and no judge who concurred in the decision having asked for rehearing, the petition for panel rehearing is DENIED.

BY THE COURT:

/s/ Edward R. Becker
Circuit Judge

Dated: Oct. 14, 1994

Supreme Court, U.S.
FILED
No. 94 1070 DEC 16 1994
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

PATRICIA INGRAM, *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

(PART II—OPINIONS OF DISTRICT COURT)

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APPENDIX III-A

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

MEMORANDUM

R. F. KELLY, J. October 21, 1992

[As Amended February 1, 1993]

MOTION IN LIMINE TO EXCLUDE OPINION TESTIMONY OF JANETTE D. SHERMAN, M.D.

AND

MOTION IN LIMINE TO EXCLUDE ALL TESTIMONY CONCERNING TESTS PERFORMED AT ANTIBODY ASSAY LABORATORIES

These are two motions which are part of a series of motions *in limine* filed by Defendants Monsanto, General

Electric, Westinghouse, Septa, Budd, Amtrak and The City of Philadelphia to exclude the testimony of Plaintiffs' expert Janette D. Sherman, M.D. pursuant to Rules 702, 703 and 403 of the Federal Rules of Evidence. I have chosen to deal with these two motions in one memorandum because the expert testimony produced by Defendants dealt with both motions and these motions involved matters that are closely related.

Plaintiffs proposed to offer as evidence the opinions of Dr. Sherman that:

1. Thirteen Plaintiffs were exposed to PCBs and contaminates of dielectric fluid;

2. As a result, each has suffered adverse health effects;

3. Each of these Plaintiffs is at an increased risk of developing cancer, as well as other illnesses; and

4. The Plaintiffs require regular medical monitoring.

In their motion, Defendants contend that Dr. Sherman's proposed testimony should be excluded because:

1. Her professional training and experience did not qualify her to render such opinion under Rule 702 of the Federal Rules of Evidence ("Rule 702");

2. Dr. Sherman failed to base her opinions upon a reliable scientific technique and for that reason they are inadmissible under Fed. R. Evid. 702;

3. Dr. Sherman failed to base her opinions on data upon which experts in the relevant fields reasonably rely upon and for that reason are inadmissible under Rule 703 of the Federal Rules of Evidence ("Rule 703"); and

4. Dr. Sherman's opinions are more likely to confuse or mislead the jury than to contribute evidence of probative value and should therefore be excluded under Rule 403 of the Federal Rules of Evidence ("Rule 403").

Attached as exhibits to this motion were the affidavits of Jordan N. Fink, M.D., Betty Lowell Cottle, M.D., F.A.C.A., Michael R. Weitekamp, M.D., F.A.C.P., Charles T. Lee, Jr., M.D., F.A.C.P., Paul M. Roediger, M.D., F.A.C.P., Elliott Vesell, M.D., Sc.D., Ronald J. Harbeck, Ph.D., James J. Leyden, M.D., S. Michael Phillips, M.D., Marie A. Savard, M.D. and Robert Wilson Morgan, M.D., S.M. Hyg.

Hearings were held on this and the other motions filed by the parties on July 28, 29, 30, 31 and August 3, 1992. On August 7, 1992, all parties were given the opportunity to argue the motions *in limine* and the motion for summary judgment pending before the Court. From those hearings, this Court makes the following:

FINDINGS OF FACT

1. Dr. Sherman has a bachelor's degree in both biology and chemistry and received her medical degree from Wayne State University in 1964. Sherman T. 92-93. She completed a one-year rotating internship at Wayne State Hospitals. Sherman T. 96.

2. Dr. Sherman does not diagnose, treat or care for individuals on an ongoing medical basis, and has not done so for the past sixteen years. Sherman T. 132; Sherman Dep. 53.[1] Although Dr. Sherman stated in her courtroom testimony that she maintained an office in Detroit until 1988 and that she still sees patients on a regular basis, I find that those are individuals that she is seeing in the context of litigation. Sherman T. 132. In 1976, she began to devote substantially all her time to litigation consulting work. Sherman T. 132-33.

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[1] Sherman Dep. refers to the deposition testimony of Janette Sherman, M.D. taken on May 19, May 20, June 5 and June 19, 1992.

3. Since 1976, Dr. Sherman ceased doing general internal medicine and has done mostly consulting in the field of internal medicine and toxicology. Since 1976, substantially all of the income that she generated from her professional activities has come from work in cases that were involved in litigation. Sherman Dep. 48-49; Sherman T. 133. She has been involved in over 8,000 cases since 1976, and has given over 800 depositions, nearly all of them in worker's compensation cases. Sherman T. 134; Sherman Dep. 70-71. In all but two of those cases her testimony has been for plaintiffs. Sherman T. 139-40. Dr. Sherman could not remember a single instance in which she examined an individual supposedly exposed to PCBs, where she concluded that PCBs had *not* caused adverse health effects. Sherman T. 140-41.

4. Dr. Sherman does not currently have admitting privileges at any hospital in the country and has not had admitting privileges since 1976. Sherman T. 135; Sherman Dep. 52-54. Dr. Sherman is licensed to practice medicine in Virginia, California, Hawaii and Michigan.

5. Although Dr. Sherman lists two "offices', one in Hawaii and one in Virginia, these "offices" are post office boxes; Dr. Sherman has residences in both of these locales, and has chosen to designate part of her residence as an office. Sherman Dep. 50-51. She has no office at which she can examine patients, "I use colleague's office in various places wherever it is needed."

Sherman T. 94.

6. Dr. Sherman offers herself as an expert in internal medicine and toxicology. Sherman Dep. 44. Dr. Sherman admits that she is not an expert in immunology. Sherman Dep. 229-30; oncology, Sherman Dep. 361; neurology, Sherman Dep. 592; psychiatry, Sherman Dep. 593; dermatology, Sherman Dep. 690; epidemiology, Sherman Dep. 711-12; and "exposure assessment", Sherman Dep. 174-75.

7. Dr. Sherman is not board-certified in any medical discipline, including the two in which she claims to be an expert. Sherman T. 137-39. She testified that she was board-certified in general medicine as a result of passing the National Board of Medical Examiners' test in 1975. Sherman T. 138; Sherman Dep. 56. However, this test is merely a qualifying examination for licensure as a medical doctor, and is normally taken by seniors in medical school. This is not a certification of any kind. Fink T. 21; Morgan T. 106.

8. Dr. Sherman testified that she is "Board-eligible" in internal medicine. However, she has never taken that board examination, and has no intention of doing so. Sherman T. 136; Sherman Dep. 55.

9. Dr. Sherman testified that she became an expert in toxicology in "the 80s" through experience, reading, writing, teaching, evaluating patients [and] course work. Sherman Dep. 413. Dr. Sherman took no toxicology courses in medical school and her training does not indicate that she is an expert in that discipline. Roediger T. 108. She is not board-certified in toxicology. Sherman T. 137.

10. Defendants at the motion *in limine* hearing called Dr. Jordan Norman Fink, M.D. Dr. Fink graduated from the University of Wisconsin with a B.S. degree in 1956 and M.D. degree in 1959. He completed a one-year rotating internship at Mt. Sinai Hospital in Milwaukee and a three-year residency in internal medicine at Marquette University in Milwaukee. He is currently a Professor of Medicine and Chief of the Allergy Immunology Division at the Medical College of Wisconsin. For the past twenty-five years, he has been involved in research dealing with immune responses of the lung, unusual lung diseases and experimental models of those lung diseases. Over the years, he has produced approximately 237 publications in peer review journals and scientific journals. He is licensed to practice medicine in Wisconsin, California and Ari-

zona. He is currently on the committee at the Medical College of Wisconsin that oversees clinical practice. He is board-certified in internal medicine, allergy and immunology. He currently teaches immunology at the Medical College of Wisconsin. His medical practice currently involves seeing approximately 16 new patients a week and about 100 return visits per week of other patients. Fink T. 13-16.

11. Dr. Fink testified that Dr. Sherman is unqualified to offer expert testimony in the fields of internal medicine or immunology. Fink T. 19-20, 28. In support of that opinion, he testified that she did not adhere to the principles of internal medicine in reaching her conclusions, and that her deposition testimony displayed fundamental deficits in her knowledge of internal medicine. Fink T. 20. Dr. Fink recounted numerous errors on basic medical terminology and principles made by Dr. Sherman, and concluded that these fundamental errors indicate Dr. Sherman's lack of qualifications. Fink T. 22-27. He testified that Dr. Sherman exhibited "major deficits" in medical knowledge and that "these items should be in the forefront of knowledge of any internist, any resident, and any medical student." Fink T. 27. He also testified that Dr. Sherman's own testimony shows that she does not understand the functioning of the immune system; does not understand the immune tests that she ordered and purported to rely upon; and that she is not qualified to interpret those tests. Fink T. 28, 33, 36, 38. In addition, Dr. Fink testified that Dr. Sherman did not appear to follow any methodology other than to blame all Plaintiffs' illnesses on PCBs. Fink T. 40, 42-43. She failed to consider alternative causes for the Plaintiffs' various illnesses, and that failure renders unreliable her opinion that these illnesses were caused by PCB exposure. Fink T. 41-42. According to Dr. Fink, the consideration of alternative causes in evaluating a disease or condition is "the basic practice of internal medicine." Fink T. 43. Dr. Fink also testified that Dr. Sherman's use of and reliance on certain

immunological data obtained from Antibody Assay Laboratories ("AAL") for ten of the Plaintiffs in this case was unacceptable medical practice. He testified that the AAL data, which form a substantial basis for Dr. Sherman's opinion, are not reliable, and not of the type reasonably relied upon by experts for the purposes Dr. Sherman attempts to use them. Fink T. 36, 44. Indeed, Dr. Fink testified that "no physician would order these tests in the absence of any clinical evidence of an immunological abnormality." Fink T. 45-46.

12. Defendants also called Dr. Paul Roediger as an expert witness at the *in limine* hearing. Dr. Roediger graduated from Princeton University in 1954 with a B.A. degree and from Jefferson Medical College in 1958 with a M.D. degree. He completed a one-year rotating internship at Abington Memorial Hospital and a three-year additional residency in internal medicine. After that he entered into medical practice at Abington Memorial Hospital and in 1963 was appointed Director of Medical Education and remains in that position at the present time. He spends about 20 hours a week controlling the administrative aspects of the 80 residents in training at Abington Memorial Hospital. He was appointed Physician and Chief of General Internal Medicine in 1972 and holds that position at the present time. He is board-certified in internal medicine. Roediger T. 94-97.

13. Dr. Roediger testified that Dr. Sherman was not qualified as an expert in internal medicine, toxicology, or immunology. Roediger T. 98-99, 108, 114. He testified that Dr. Sherman could not receive admitting privileges at Abington Memorial Hospital, Roediger T. 103, and that Abington standards for granting privileges were similar to those employed in most hospitals across the country. Roediger T. 99-101. Further, he agreed with Dr. Fink's testimony regarding Dr. Sherman's ignorance of the basic principles of internal medicine, and cited an additional example that Dr. Sherman did not know the difference

between plasma and serum. Roediger T. 108-09. Dr. Roediger also testified that Dr. Sherman did not follow reliable methodology in formulating her opinion in this case since she did not order standard laboratory tests for any of the Plaintiffs, examined only three of the thirteen Plaintiffs on whom she opines, and failed to consider alternative causes. Roediger T. 119-22.

14. Dr. James Leyden was also called by Defendants as an expert in the field of dermatology. He graduated from the University of Pennsylvania Medical School in 1966 and completed a residency in dermatology at Penn where he later joined the faculty and for fifteen years he has had the additional responsibility of being the Chief of the Dermatology Clinic. He currently sees patients, teachers and does research. He sees on the average approximately 120 patients a week. Dr. Leyden has been a full professor at Penn Medical School since approximately 1983 and is board-certified in dermatology. In the field of research, on two occasions, he has won the gold medal from the American Academy of Dermatology. Leyden T. 143-47.

15. Dr. Leyden testified that Dr. Sherman was not an expert in dermatology, and was not qualified to diagnose chloracne or any dermatologic condition. Leyden T. 152. He described the marked difference between chloracne, a condition associated with exposure to halogenated hydro carbons, and acne vulgaris, which is common acne. Leyden T. 153-54, 156-57. He testified that any physician qualified to diagnose dermatologic conditions would easily be able to distinguish between the appearance of those two conditions. Leyden T. 154. As a matter of fact, Dr. Leyden testified that he could tell the difference between the two conditions at fifty paces. Leyden T. 160. Since Dr. Sherman testified that the two conditions are identical in appearance, Dr. Leyden found that she plainly was not qualified to diagnose chloracne in any of the Plaintiffs in this case. Leyden T. 154-55. Dr. Leyden

pointed out that Dr. Sherman's methodology in making such diagnoses was nonexistent. Leyden T. 157.

16. Defendants called an expert witness, Dr. Ronald Harbeck, who is the Director of the Clinical Laboratories, the Director of the Diagnostic Immunology Laboratory and a member of the Department of Medicine at Ashland Jewish Center for Immunology and Respiratory Medicine in Denver, Colorado. He holds appointments to three departments at the University of Colorado School of Medicine, those being the Department of Pathology, Microbiology and Department of Medicine. The National Jewish Center for Immunology and Respiratory Medicine is an institution which conducts research in respiratory diseases and immunology. Its research programs are recognized world-wide and has recently been mentioned as one of the top ten independent research institutions in the United States. Dr. Harbeck performs immunology testing on a daily basis. He has over 65 publications in peer review journals and has written a textbook in diagnostic immunology which was published in 1991. He is board-certified by the American Academy of Microbiology and has a Ph.D. in microbiology. Harbeck T. 73-75.

17. Dr. Harbeck's testimony was directed toward the immunologic data that Dr. Sherman ordered from AAL. He testified that the AAL results were totally unreliable, and would not be relied upon by experts for any conclusion. Harbeck T. 76. He explained that AAL has not received accreditation from the College of American Pathologists ("CAP"), and that the quality control procedures it used were totally inadequate. Harbeck T. 84.[2] He explained the reasons for the CAP accreditation program and that the test results of a lab which fails to obtain this accreditation are unreliable. Harbeck T. 85-86. He also noted that AAL did not follow accepted

[2] Dr. Harbeck has inspected labs on behalf of CAP. Harbeck T. 84.

laboratory methodology in performing several standard analytic procedures. Harbeck T. 81-82. Dr. Harbeck concluded that any results obtained by AAL were completely untrustworthy. Harbeck T. 86.

18. Robert W. Morgan, M.D., S.M. Hyg., is a graduate of Harvard University School of Public Health and the University of British Columbia School of Medicine. He is certified in occupational medicine by the American Board of Preventive Medicine and he is a Fellow of The American College of Epidemiology. He has taught both preventive medicine and epidemiology at the University of Toronto, and he has served as Director of the Stanford Research Internal Center for Community Health Studies. He has published in the fields of occupational health, preventive medicine and epidemiology. Dr. Morgan testified that Dr. Sherman "doesn't have the qualifications that one would normally expect of an internist," and that she also was not qualified in the field of occupational medicine. Morgan T. 107-13. He noted that Dr. Sherman had not practiced clinical medicine for 16 years, and cited several errors in basic anatomy and immunology that Dr. Sherman made at her deposition. Morgan T. 111-13. Dr. Morgan also testified that Dr. Sherman did not employ any reliable methodology in concluding that PCB exposure was the cause of the various illnesses of which the Plaintiffs complained. Morgan T. 108.

19. Michael R. Weitekamp, M.D., F.A.C.P., is Chief of the division of General Internal Medicine at Hershey Medical Center and is an associate professor of medicine at the Pennsylvania State University Medical School. From 1985 to 1990, he was Chairman of the Department of Medicine at the Polyclinic Medical in Harrisburg, Pennsylvania. He graduated from Georgetown University Medical School and was trained in internal medicine and infectious diseases at Hershey Medical Center. Dr. Weitekamp is certified by the American Board of Internal Medicine in both internal medicine and infectious dis-

eases, and actively engaged in the practice and teaching of both of these disciplines. Dr. Weitekamp is a member of the Penn State Department of Medicines Resident Clinical Competency Committee, and he serves on the Medical Education and Quality Assurance Committees of the Polyclinic Medical Center. Dr. Weitekamp testified that Dr. Sherman was unqualified in the fields of internal medicine and immunology. Weitekamp T. 32, 51. He noted many errors regarding basic principals of internal medicine and immunology that Dr. Sherman made in her deposition. Weitekamp T. 36-37, 39, 51. He stated that most of the medical students and residents under his supervision would not make such errors. Weitekamp T. 38-39. Dr. Weitekamp also testified that Dr. Sherman's failure to perform differential diagnoses for the Plaintiffs' illnesses constitutes a violation of "the whole process that is really the hallmark of the internist," and thus her methodology is totally unreliable. Weitekamp T. 62.

20. Dr. Stanley M. Phillips was called on behalf of Defendants as an expert in internal medicine, immunology and allergy. Dr. Phillips is currently employed at the University of Pennsylvania Medical School as a full time professor of medicine with a subpecialty of allegery and immunology at the University of Pennsylvania. Phillips T. 3. He is a senior scholar in clinical epidemiology at University of Pennsylvania and a senior consultant in medicine and allergy in immunology at the Philadelphia Veterans Administration Hospital and a consultant to the Smith-Kline Beckman Corporation in the field of immunology. He has served on the faculties of Harvard University and George Washington University. He has edited two books and over a hundred publications in peer review journals, and has served on the editorial board of review of the American College of Physicians. He has served on the editorial board of the Journal of Immunology, the Journal of Allergy and Clinical Immunology, and the journal of clinical investigation in the New England Journal of Medicine. In addition to his responsibili-

ties at the University of Pennsylvania Medical School, he spends a third of his time in clinical practice taking care of patients in private practice where he sees patients with internal medicine problems as well as allergy immunology problems. Phillips T. 3-8. Dr. Phillips testified that the immunology test ordered by Dr. Sherman and performed by AAL are of no clinical significance, and are neither important nor meaningful in the clinical evaluation of a patient. Phillips T. 10. In fact Dr. Phillips testified that the tests "probably would be more misleading and dangerous than helpful." Phillips T. 10. According to Dr. Phillips, many of the tests performed by AAL have no clinical significance, are useless for any clinical purposes, and would not be performed by any reputable laboratory. Phillips T. 17-20. Dr. Phillips further testified that AAL test results are not scientifically valid, that such tests are not reasonably relied upon by the medical or scientific community, and that the methodology utilized by AAL in performing the tests were completely unreliable. Phillips T. 17-21, 27, 35, 41.

21. In her deposition testimony, Dr. Sherman states that John Ingram, Jr.'s myelin auto-antibodies reflect "damage to his myelin cells, which are on the central nervous system." Sherman Dep. 259. Dr. Fink testified that "myelin is a lipid coating of the nerve fibers. There is no such animal as a myelin cell. Myelin is made by a cell called Schwann's cell." Fink T. 24-25; *see also* Morgan T. 111-12; Weitekamp T. 37-38.

22. Dr. Sherman states that the difference between plasma and serum is that "[p]lasma has the proteins removed." Sherman Dep. 143. Serum, not plasma, has the proteins or clotting factors removed. As Dr. Roediger testified, any medical student or resident would know the difference between the two. Roediger T. 109; *see also* Weitekamp T. 38.

23. According to Dr. Sherman, deoxyribonucleic acid ("DNA") consists of four base pairs—"adonine, guani-

dine, thymidine and uridine." Sherman Dep. 359. This is wrong—Dr. Sherman omitted cytosine, and inserted uridine, which is not found in DNA. Weitekamp T. 38-39. This mistake is particularly noteworthy because Dr. Sherman has testified that PCBs interact with DNA to produce mutations which ultimately cause cancer in humans. Sherman Dep. 351-58.

24. Dr. Sherman testified that candida infections are not common in young children. Sherman Dep. 856. In fact, candida, one of the causes of diaper rash, is very common in young children. Weitekamp T. 58-59.

25. A large part of Dr. Sherman's medical opinions in this case were based on the results of immunological tests by AAL which she ordered for ten Plaintiffs. She testified that she found "an overall pattern throughout these ten people of serious derangement of immunological function. And more than likely, I believe you will see an increased rate of malignancy among these people, which is, I believe, reflected early by the abnormal findings." Sherman Dep. 648. However, when asked about those tests at Sherman Dep. 298,

> Q. What are the different things that they measure?
>
> A. That you'll have to ask Dr. Broughton.

Again at Sherman Dep. 300,

> Q. What is the predicted significance of an elevated lymphocyte test stimulated by PHA?
>
> A. You'll have to ask Doctor Broughton for that —what those sophisticated tests mean.

Again at Sherman 300,

> Q. OK, now does the measure of the T cells reflected in the PHA stimulation have for you any significance in predicting future health defects of an individual?
>
> A. I don't know.

See also Sherman Dep. 305-07, 473, 646-48, 944.

Dr. Sherman is not board-certified in immunology, and she admits that she is not an expert in that field. Sherman T. 137; Sherman Dep. 229-30.

26. As to the significance of the TA1 positive cells [CD 35], she noted that it is "one of the subsets of the T helper cells," but beyond that, Dr. Sherman did not have any other information. Sherman Dep. 470-72. As to [why] one would order such a test she replied, "[Y]ou'll have to ask Dr. [Broughton]." Sherman Dep. 473.[3]

27. Dr. Sherman was not qualified to interpret the results of those tests. Fink T. 28. [Dr. Sherman "admits that she is not [an expert in immunology] and I believe from her testimony that she absolutely is not competent to analyze immune tests . . . ."]; Roediger T. 116-17; Weitekamp T. 60. This point is conceded by Dr. Sherman in her deposition. Sherman Dep. 646-48, 944.

28. At times, Dr. Sherman assigns incorrect meanings to certain of the immune tests. She states, for example, that the anti-nuclear antibody tests tell one "that there has been antigenic damage to the nuclear portion of the cell," Sherman T. 211; that the anti-smooth muscle antibody tests "determine[s] if there has been any antigenic damage to the smooth muscle cells," Sherman T. 212 and that the anti-mitochondrial antibody determines "[w]hether there has been damage to the mitochondrial of the cells," Sherman T. 213.

Drs. Fink, Phillips, and Weitekamp testified that all this is incorrect. Fink T. 33 [Dr. Sherman's diagnosis of "antigenic damage" to the smooth muscle cells is "a false concept that she has. There is no antigenic damage. The antigens don't damage."]; Phillips T. 15-17; Weitekamp T. 52-53.

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[3] Dr. Broughton is the director of Antibody Assay Laboratories. The Plaintiffs have not designated him as an expert and he did not testify at the *in limine* hearing.

29. Dr. Sherman states that T suppressor cells can cause B-cells to produce antibodies. Sherman Dep. 218. Dr. Fink, in his testimony, stated that that is absolutely incorrect. "Suppressor cells suppress. That is why they are called suppressor cells. They suppress antibody formations." Fink T. 34-35.

30. When asked how many classes of antibodies there are, Dr. Sherman replied, "I don't think I've counted. I don't really. I don't really know." Sherman Dep. 264. Dr. Fink testified that "There [are] five classes. Everybody knows that." Fink T. 28-29. He went on to state that that is something that a medical student would know, that it is taught in all medical schools and taught in continuing medical education courses. Dr. Sherman stated also that she could not remember the difference between IgG and IgM, or the significance of IgE. Sherman Dep. 330, 470. As Dr. Fink testified, this is "an insult" because it is "absolutely basic immunology." Fink T. 29-30.

31. The proper methodology in determining the cause of a particular individual's illness is to examine first for the most common causes of that condition. Only after eliminating those causes can one move to the more remote causes. Roediger T. 119-121. According to Dr. Roediger, the answers that Dr. Sherman gave in her testimony do not reflect an understanding of the common identifiable causes for diseases of hypertension, diabetes and asthma. Roediger T. 121.

32. According to Dr. Sherman, there are two types of asthma: "fatal and non-fatal." Sherman Dep. 438 ("that's all I can think of"). She also states that the known causes of asthma include "profound respiratory infection," "exposure to some of the organo phosphate pesticides" and "damage to the lung for whatever reason." Sherman Dep. 437. As Dr. Fink states, there are two types of asthma, extrinsic and intrinsic, not "fatal" and not "non-fatal." Fink T. 26-27. Dr. Weitekamp explained that it is erroneous and meaningless to classify asthma or any

other disease process as "fatal" or "non-fatal." Weitekamp T. 42-43. Dr. Fink termed that distinction "silly." Fink T. 26.

33. According to Dr. Sherman, the only causes of hypertension are "endocrine, anatomical abnormalities of the kidney, chronic kidney infection and xenobiotic damage to the kidneys." Sherman Dep. 206-07. Almost all of the hypertension seen in our society is called "essential hypertension," the cause of which is unknown. Weitekamp T. 46; Fink T. 22-23; Morgan T. 108. Furthermore, as to the known causes of hypertension, Dr. Sherman omitted family history and lifestyle, two of the most prevalent known causes. Fink T. 22-23.

34. According to Dr. Sherman, the only causes of diabetes are "chemicals and radiation." Sherman Dep. 443 ("I can't think of anything else"). As to this, Dr. Fink states, "it's common in internal medicine to know that diabetes is an idiopathic disease and we don't know the cause. Except in the juveniles, where diabetes may be an immune disorder in which antibodies are formed against the cells which manufacture the insulin." Fink T. 26; *see also* Weitekamp T. 43.

35. According to Dr. Sherman, hyperpigmentation is due to "T cells which start in the thymus" carrying cells to the skin, and those T cells cause the pigmentation. Sherman Dep. 245-46. Dr. Fink states, "this doesn't make sense. That's wrong." Fink T. 24; *see also* Morgan T. 111 ("I have never heard any theory even remotely resembling that."); Weitekamp T. 44.

36. Drs. Weitekamp and Roediger explained that in ordering and interpreting medical tests, one must understand the concepts of "sensitivity" and "specificity." As Dr. Roediger states, if a physician does not understand these concepts, she cannot order or interpret any type of medical tests. Roediger T. 113-114; *see also* Weitekamp T. 57 ("I don't think you can apply a test to clinical

practice, unless you have an understanding of sensitivity and specificity."). Dr. Sherman admits that she does not know the difference between these two terms. Sherman Dep. 566. (Q. Doctor, do you know what is referred to as the sensitivity of a test? A. No. Q. What about the specificity of a test? Do you know what that refers to? A. No.) Dr. Sherman also did not know what a positive or negative predictive value means. Sherman Dep. 567. She does not know the distinction between "incidence" and "prevalence". Sherman Dep. 715-16. All of these are distinctions commonly made by and well known to physicians. Roediger T. 111-12; Weitekamp T. 57. Dr. Weitekamp explained that without this basic knowledge, Dr. Sherman is not only unqualified to order and interpret specific diagnostic tests but she also is incompetent to design a medical monitoring plan. "I would have to say that somebody who doesn't seem to have a firm foundation in clinical epidemiology, which includes an understanding of sensitivity, specificity and predictive value of testing, that individual should not be making recommendations for screening tests." Weitekamp T. 70. Those made by Dr. Sherman are "certainly not" based upon recognized scientific technique or data internists reasonably rely upon. Weitekamp T. 71.

37. Dr. Sherman testified that she can distinguish between chloracne, a skin condition associated with heavy exposure to halogenated hydrocarbons, and common acne (acne vulgaris). She opined that two Plaintiffs may have suffered from chloracne. Yet, she cannot describe the difference in appearance between chloracne and common acne. Sherman Dep. 686-87. As explained by Dr. James J. Leyden, Professor of Dermatology at the University of Pennsylvania School of Medicine and one of the four or five nationally recognized experts on acne, the characteristics and distribution of the lesions of these two forms of acne are totally different, and their appearance on biopsy is distinct. Leyden T. 147-49, 153.

38. Dr. Sherman testified that she has seen chloracne and "[i]t looks like your standard so-called teenage acne." Sherman Dep. 686. But Dr. Leyden testified, "that's not correct at all . . . chloracne is very distinctive." Leyden T. 153. Dr. Leyden also testified that Dr. Sherman was plainly wrong in stating that "we don't know whether ordinary teenage acne isn't really chloracne, you see, without a history you don't know." Sherman Dep. 687. As Dr. Leyden stated, "she may not know, but those of us who work in this field sure do know the difference and we know how to tell the difference by looking, and we've known how to do that for a long time." Leyden T. 154. Asked whether his residents could distinguish acne from chloracne, Dr. Leyden responded, "Yes, absolutely. In fact, if they didn't . . . I'd feel compelled to resign." Leyden T. 154.

39. At the hearing, Dr. Leyden displayed two color photographs—one of a man with chloracne, and one of a man with common acne. *See* Defendants' *In Limine* Exhibit 6. The difference between the two conditions is striking. Dr. Leyden testified that any physician who purports to be able to diagnose chloracne can easily distinguish between that condition and acne vulgaris. Leyden T. 154. He concluded that since Dr. Sherman cannot make that distinction, she is clearly unqualified to diagnose any of the Plaintiffs with chloracne. Leyden T. 155.

40. Drs. Fink, Weitekamp, Roediger, Leyden, and Morgan uniformly concluded that Dr. Sherman is not qualified to offer an expert opinion in internal medicine, toxicology, immunology, or any other field of medicine. Fink T. 19-20, 28, 36, 38; Weitekamp T. 32, 60; Roediger T. 98-99, 108, 114; Leyden T. 152; Morgan T. 107, 111, 113. By virtue of their own experience and training, their responsibility for teaching medical students and residents, and the roles they play in evaluating both students and other physicians, these physicians are emi-

nently qualified to determine what qualifications are necessary before one can be considered an expert in their respective fields of medicine.

41. In support of their conclusion, these doctors all pointed to Dr. Sherman's lack of formal qualifications, her sixteen-year absence from the clinical practice of medicine, and the impact that has on her current knowledge of medicine. Roediger T. 98-104; Weitekamp T. 60. They find that this lack of training and experience manifests itself in Dr. Sherman's failure to understand basic concepts of internal medicine, failure to understand the immune system tests she ordered from AAL, and misinterpretation of the significance of the immune test results. In particular, Dr. Fink described her theory that the immune system is not activated unless there is "damage to the cells" as totally false—according to Dr. Fink, this reflects a fundamental misunderstanding of the human immune system. Fink T. 33, 38. The experts found her unqualified to be on their respective hospital or lab staffs, unqualified to diagnose medical conditions, and unqualified to treat patients. This evidence is persuasive. The Court finds that Dr. Sherman is not qualified as an expert in any field of science or medicine, and her testimony would be of no assistance to the trier of fact.

42. For ten Plaintiffs, Dr. Sherman bases her opinions solely on her review of medical records and of questionnaires completed by the Plaintiffs and their attorneys. Sherman T. 144. Dr. Sherman examined only three of the thirteen Plaintiffs as to whom she offers opinions.[4] Sherman T. 143.

43. Dr. Sherman did not order any of the standard medical or laboratory testing that would typically accompany an ordinary physical examination, such as standard blood chemistry, urinalysis, liver function, kidney function, or pulmonary function tests. Sherman T. 150-51, 153-54.

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[4] Amber Burell, Andre Williams and Bessie Cunningham.

She did not ask that any Plaintiff be tested for PCBs or any of the "contaminants" of dielectric fluids that she contends caused them to suffer alleged adverse health effects. Sherman Dep. 34.

44. The only tests Dr. Sherman requested were immunology "tests" offered as part of a "Chemical Injury Kit" by AAL which is located in Santa Ana, California. Sherman T. 150, 154.[5] She selected AAL because of the favorable experiences she had with that lab and its director in the past. Sherman T. 151. Yet, there are several reliable labs in the Philadelphia area which could have performed the immune tests Dr. Sherman requested. Phillips T. 36. The AAL "Kit" was shipped to Plaintiff's counsel. Dr. Sherman does not know whether the "Kit's" instructions were followed, when or how the Plaintiffs' blood was drawn, or when the blood was shipped to California. Sherman T. 156; Sherman Dep. 287 ("I was not there.")

45. With the exception of the three Plaintiffs who she examined, the only information Dr. Sherman had about these Plaintiffs were certain medical records provided by Plaintiffs' attorneys and the AAL results. With the exception of two of the thirteen Plaintiffs, none of the treating physicians even mentioned PCBs in the Plaintiffs' medical records (Sherman T. 147), much less concluded that PCBs caused any illness. Dr. Sherman admits that in reviewing medical records she did not make her own differential diagnoses apart from those made by the treating physicians. Sherman T. 161.

46. Nonetheless, Dr. Sherman cites exposure to PCBs as a "significant contributing cause" of virtually every

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[5] Dr. Sherman said she believes all of the Plaintiffs should have a complete history and physical, complete blood count and differential, an "SMA-12," and "lipids," before trial—but she has not yet requseted that these tests be run. Sherman Dep. 31-32. She acknowledges that she "could have" asked for these tests at the time she requested the immunology tests but did not do so. Sherman Dep. 144. She did not recommend PCB fat tests, but states they "would be a very good idea." Sherman Dep. 34, 68.

condition or illness described in the medical records she reviewed. Fink T. 40; Roediger T. 135-36. These include such common diseases as asthma, diabetes, elevated lipids, hypertension, lung disease, heart disease, cancer, respiratory infections, interference with the immune system, heart attacks, elevated liver function tests, arthritis, pain in the joints, headaches, sinusitis, skin rashes, and various other illnesses. *See* Sherman Report dated April 6, 1992.

47. In this case, Dr. Sherman has failed to utilize any reliable process to form opinions as to the relationship between any alleged exposure to PCBs and any of Plaintiffs' alleged health effects. As Dr. Fink testified, she simply blamed everything—even the most common illnesses—on PCBs. Fink T. 40-42.

48. Asked to describe Dr. Sherman's methodology, Dr. Fink testified, "I couldn't find any." Fink T. 43. Dr. Fink pointed out that it is standard medical practice to first perform a physical, obtain the necessary test results, and make a differential diagnosis, but Dr. Sherman did not follow these procedures. Fink T. 17-19. "She went from patient complaint to PCBs. Made no difference what the patient said, it was PCBs. That's not accepted medical practice." Fink T. 40. "[W]hen she was asked about alternative causes, she said there were none, it was all PCBs." Fink T. 42.

49. Dr. Roediger explained that Dr. Sherman only examined three patients; she did not examine any of the other individuals involved in the litigation. Roediger T. 118-21. He testified that it is "standard medical practice" to do a physical examination before forming a medical judgment, and that a physician cannot base a differential diagnosis solely on a review of pre-existing medical records. Roediger T. 122-24.

50. Dr. Leyden testified that he was unable to discern that Dr. Sherman followed any methodology in reaching

the conclusion that two Plaintiffs suffered from chloracne. She just "seemed to declare it as an example of chloracne." Leyden T. 157.

51. Dr. Weitekamp testified that "[i]t certainly was not apparent from her testimony" that Dr. Sherman actually performed a differential diagnosis on the Plaintiffs. Weitekamp T. 65. "[H]aving read the testimony and having seen how she tried to link each of those various complaints to PCB exposure, without really entertaining other possible causes, I would say that that's inappropriate." Weitekamp T. 66. "It's shooting from the hip, very opinionated. I don't know any other way to describe it." Weitekamp T. 66. "I do not feel that she used reliable scientific technique in formulating her opinions." Weitekamp T. 67.

52. Dr. Weitekamp testified that Dr. Sherman's methodology is equally flawed with respect to her medical monitoring opinions. Those opinions are "certainly not" based upon reliable scientific technique. Weitekamp T. 70-71.

53. Dr. Morgan testified that he was not aware that Dr. Sherman based any of her opinions on "any methodology." Morgan T. 103. "I couldn't detect any methodology." Morgan T. 108.

54. As Drs. Fink, Roediger, Weitekamp, and Morgan testified, a differential diagnosis—where the physician either rules in or rules out alternative causes for diseases—is the hallmark of internal medicine. According to Dr. Fink, considering alternative causes is "the basic practice of internal medicine. That's what the internist does, makes a diagnosis by taking the entire picture, outlining what the possibilities [are] and then honing down based on his knowledge and experience and literature that he has read, et cetera, in making a diagnosis." Fink T. 43; *see also* Roediger T. 118; Weitekamp T. 60-62; Morgan T. 109. These doctors explain that in making a determination as to the cause of a disease, an internist must start with the

most common causes of the condition. Only after eliminating those causes can more esoteric causes he considered. Roediger T. 117-19.

55. Dr. Sherman does not follow this procedure. She assigns PCBs as the cause of a disease and does not consider, and rule out, *any* alternative causes. For instance, although she testified that PCBs caused the following illnesses, she conceded that she did not consider and rule out any alternative causes for these illnesses:

John Ingram, Sr.'s hypertension, Sherman T. 149-50;

John Ingram, Sr.'s elevated T. suppressor and T helper cells, Sherman T. 152-53;

Charles Stanbach's stomach cancer, Sherman Dep. 388;

Patricia Ingram's asthma, Sherman T. 157-58;

Patricia Ingram's diabetes, Sherman Dep. 444-45;

Ten Plaintiffs' "overactive immune systems," Sherman Dep. 640-41;

Andre Williams' episcleritis, Sherman T. 165;

Patricia Burrell's dizziness, Sherman Dep. 698;

Matthew Cunningham's anemia, Sherman T. 165-66.

In fact, as Dr. Fink correctly noted, Dr. Sherman did not conduct any meaningful evaluations of possible diseases and attempt to consider or rule out those causes. Fink T. 42-43.

56. Dr. Sherman examined only three of the thirteen Plaintiffs on whom she offers an opinion in this case. As to the ten she did not examine, Dr. Sherman conceded that she did not perform differential diagnoses for *any* of the illnesses documented in their medical records. Sherman T. 160-62. She purports to rely on these medical records as the sole basis for her opinion that PCBs caused these Plaintiffs' past and present conditions, claiming that

the treating physicians performed the required differential diagnosis. Sherman T. 159-62. Yet, with two possible exceptions, *none* of the treating physicians found that PCBs were associated in any way with their patients' illnesses. Sherman T. 147. Dr. Sherman's explanation for this—that the treating physicians did not know about the Plaintiffs' PCB exposure—is not credible, since she admitted that she has never spoken to any treating physician. Sherman T. 147-48.

57. In this case, where she did not examine ten out of thirteen Plaintiffs about whom she testified, Dr. Sherman purported to rely on the Plaintiffs' medical records in making her judgment (even though those records did not include any finding that PCBs caused any of these problems). Dr. Sherman testified before this Court that "of course" it was "generally accepted" to rely on such medical records. Sherman T. 120. Yet earlier this year, in a case in Florida where Dr. Sherman had not reviewed the medical records of certain plaintiffs before rendering her opinion, she testified that such records are unreliable for this purpose. In *Woodman v. United States*, on direct examination by plaintiffs' attorney, Dr. Sherman gave the following sworn testimony:

> Medical records, oh, my, they are very difficult to use because frequently the patient goes in with roaring diarrhea and they have also got a headache, the doctor is making all of his attention, or her attention on the diarrhea, don't ask about the headache, many times, at least a lot of the records I read are almost illegible. Many physicians don't do a review of systems, they only attend to the immediate problem that the person is in there for. Many times patients, if they have been in six times to complain of the same thing don't say anything anymore, they get discouraged and just figure, well, there is no point.

Woodman testimony, February 18, 1992, p. 55. Then she gave the following point-blank answers to questions from the trial judge:

The Court: I'm really—I'm perplexed, Dr. Sherman, with respect to Steven, and I think it's Candra who had an examination. I have understood that you take the position that, in your professional judgment, the most reliable source for your diagnosis is your personal interview with the physical examination of a patient.

The Witness: Yes.

The Court: That you do not rely upon preexisting medical records because of the propensity toward inaccuracy.

The Witness: That's correct.

The Court: Bias and so forth.

The Witness: Mostly omissions.

The Court: I believe that you said that surgery and pathology reports are generally—you had found them accurate.

The Witness: And hospitalization reports.

The Court: But day-by-day medical records kept by your colleagues in the profession are not reliable for the purposes that you're here to testify.

The Witness: In general, that is correct.

Woodman testimony, February 19, 1992 p. 24-25. Dr. Sherman conceded on cross-examination that she had in fact given that testimony. Sherman T. 171. It appears to this Court from this and other examples that Dr. Sherman will give whatever testimony may be convenient in any particular case.

58. For example, Dr. Sherman examined three Plaintiffs on April 23, 1992. On June 18, 1992, Defendants moved to preclude Dr. Sherman from testifying at trial

with respect to these physical examinations because they were performed in violation of this Court's June 4, 1991 Scheduling Order and after this Court's April 10, 1992 Order denying Dr. Sherman permission to perform late examinations. On July 2, 1992, in response to Defendants' motion to preclude her testimony concerning her examinations of Andre Williams, Bessie Cunningham, and Amber Burrell, counsel for Plaintiffs represented to the Court that they had no knowledge of this Court's April 10th Order at the time Dr. Sherman performed her examinations. Plaintiffs correctly noted that this Court's Order was actually entered on April 24, 1992. Specifically, they represented in their papers:

> In reliance upon defendants' proposed [alternative] deadline, *plaintiffs arranged to have Dr. Sherman complete her examinations on April 23, 1992* . . .
>
> Plaintiffs could not and did not learn of this Court's Order precluding medical examinations until *after it was entered on April 24, 1992.*

Plaintiffs' Memo. at 2-3 (emphasis supplied). Dr. Sherman, however, testified under oath that she limited her April 23 examinations to three Plaintiffs because the Plaintiffs had not yet received the Order. Dr. Sherman testified, "My understanding is that *the Court* had said that I could not examine these people." Sherman T. 154 (emphasis supplied). "[*S*]*ince there was a forbiddance of seeing everybody*, I think we tried to get one child, one woman and one man." Sherman T. 163 (emphasis supplied). She also claimed that she refrained from ordering conventional blood tests or other laboratory tests for Plaintiffs because of the April 10th order. Yet, Dr. Sherman had both completed her examinations of Williams, Cunningham, and Burrell and ordered the AAL tests *before* she had any knowledge of the Court's Order. In addition, Dr. Sherman had more than a year to examine the Plaintiffs before their Rule 26(b)(4) Statement was due on March 17, 1992. Sherman T. 142-43.

59. It was clearly Dr. Sherman's decision, not the Court's order, that caused her to refrain from performing other examinations or ordering additional lab tests.

60. As to the three Plaintiffs Dr. Sherman did examine, she claims to have made her own differential diagnosis in reaching the opinion that PCBs caused their various adverse health effects. Sherman T. 116-18. Even though Dr. Sherman's written medical reports for these three Plaintiffs did not contain a differential diagnosis, she asserts that she excluded alternative causes in her head. Sherman T. 120-21. However, at her deposition she testified under oath that she did not consider any alternative causes for Andre Williams' episcleritis. Sherman Dep. 679. Dr. Sherman's inconsistent testimony leads this Court to find her not credible as a witness.

61. It is apparent that in every one of her "diagnoses" Dr. Sherman did not consider and rule out alternative causes for the Plaintiffs' conditions—even though all of the Plaintiffs exhibit characteristics (*e.g.*, family history of disease, obesity, smoking, etc.) which, as Dr. Sherman also concedes, are known to cause the various injuries they allege. For each of these relatively common conditions there are numerous causes more generally agreed upon and accepted by the scientific medical community than Dr. Sherman's theories on PCBs. Weitekamp T. 65.

62. An example of Dr. Sherman's unscientific methodology can best set forth quoting directly from her deposition, Sherman Dep. 43,

> Q. Have you ruled out any causes of asthma other exposure to transformer fluid in the case of Patricia Ingram?
>
> A. No.
>
> Q. You have not done that?
>
> A. That's what I just said.

Again at Sherman Dep. 439,

> Q. Do you know of any support in the literature, Doctor, for the proposition that exposure to PCBs causes asthma?
>
> A. Yes.
>
> Q. What is that?
>
> A. I already quoted it to you, that was the Battleboro article.
>
> Q. Do you have that article with you Doctor?
>
> A. No.

* * * *

Again at Sherman Dep. 440,

> Q. Could you spell the author?
>
> A. B-A-T-T-L-E-B-O-R-O.

That questioning took place May 20, 1992. During Dr. Sherman's deposition on June 19, 1992, the questioner, Mr. Cox, returned to the subject as follows on page 99:

> Q. You identified a study by Battleboro or a reference by Battleboro as supporting your contention that PCBs were found to be associated with asthma. Do you have that study with you today?
>
> A. I'm glad you asked me. Yes I brought it. Yes I brought in Battleboro. I beg your pardon, it refers to the Battleboro[*sic*] Press.

* * * *

Again at Sherman Dep. 996,

> Q. Dr. Sherman, you were referring at some point to what you call the Battleboro article and you produced a two page article which appears to be a newspaper article which has now been marked as Sherman 55. What is that article?
>
> A. This is from Battleboro, Vermont by a patient who contacted me after becoming ill from leaking PCB containing oils in his submersible pump.

As it turned out, the Battleboro article which Dr. Sherman referred to as associating PCBs with asthma was nothing more than a newspaper report containing the claim by an individual that he got asthma because of PCBs in his drinking water. The article indicated that the case had been dismissed from court. Dr. Sherman never met the individual named in the article and she knew nothing about his medical history. That was the basis for Dr. Sherman's assertion that PCBs have been associated with asthma. Sherman Dep. 996-99.

63. As Dr. Fink testified, and as any lay person would known, a newspaper article cannot be relied upon as support for a medical diagnosis. Fink T. 47.

64. To support her opinion on medical causation, Dr. Sherman heavily relies upon the results of immunological tests from a "Chemical Injury Kit" administered by AAL. Even though she concedes that she is not an expert in immunology, Sherman T. 137, Sherman Dep. 229-30, Dr. Sherman nonetheless purports to use this data to reach the conclusion that PCBs have caused or will cause myriad adverse health effects in Plaintiffs, including cancer. Fink T. 28.

65. Dr. Sherman selected AAL, an unaccredited facility, Harbeck T. 84-85, as the lab to analyze the Plaintiffs' blood samples because of her prior experiences with the laboratory. Sherman T. 151. Dr. Sherman chose not to use a lab from the Philadelphia area for this testing. Sherman T. 151-52.

66. Dr. Phillips and Dr. Harbeck testified that the tests performed by AAL: (1) are unreliable; (2) do not allow a scientifically acceptable procedure or methodology; and (3) include tests that are not accepted in the medical or scientific communities. The evidence and testimony presented in support of Defendants' motion *in limine* to exclude this data is not disputed. Plaintiffs produced *no* evidence and *no* witnesses to rebut that testimony. Although Dr. Sherman herself selected AAL, she pro-

vided no testimony in opposition to Defendants' evidence regarding that lab. In fact, throughout her entire direct examination conducted by Plaintiffs' counsel, Dr. Sherman did not once mention the testing by AAL or address any issues raised by Drs. Phillips and Harbeck concerning the testing procedures, methodology or results reported by AAL. Sherman T. 91-132.

67. Defendants served a subpoena upon AAL compelling the production of 35 categories of documents pertaining to AAL's laboratory procedures and methodology, quality control, chain of custody of the blood samples, and analysis of blood samples which had been drawn from ten of the Plaintiffs and submitted to AAL at the direction of Dr. Sherman. The documents produced by AAL in response to this subpoena were entered into evidence without objection by Plaintiffs' counsel.

68. Prior to testifying at the hearing on the motion *in limine*, Dr. Phillips reviewed the laboratory findings primarily from AAL, the documents which were provided by Dr. Broughton, the deposition testimony of Dr. Sherman and some additional medical literature. Phillips T. 9.

69. In response to Defendants' subpoena, AAL failed to produce any records regarding:

(a) The dose-response curves for its tests, Phillips T. 29;

(b) Data regarding the use of current control groups to check the validity of the reported test results, Phillips T. 32;

(c) Quality control data used to ensure the validity of the testing, Phillips T. 37;

(d) Any documentation regarding when the blood samples were drawn, Harbeck T. 80-81; or

(e) The chain of custody regarding the Plaintiffs' blood samples, Harbeck T. 81.

70. Dr. Sherman testified that she has no personal knowledge regarding the circumstances under which the blood samples were drawn for AAL, when the blood samples were drawn, or when the blood samples were sent to AAL for analysis. Sherman T. 156.

71. Dr. Phillips testified that in the absence of clinical correlation, immunological tests are not "biologically relevant" or meaningful to the clinical evaluation of a patient. Phillips T. 10. In fact, "they probably would be more misleading and dangerous than helpful." Phillips T. 10. Dr. Phillips further testified that the presence of an abnormal test result on the types of test performed by AAL does not establish the presence of a disease and it does not establish a causual relationship between a disease and the cause of the disease. Phillips T. 11.

72. Dr. Phillips explained that there are numerous confounding factors that may produce positive results in the type of tests performed by AAL: "[I]f for example a patient is under stress, psychological or physical stress. If the patient has been drinking alcohol. If the patient has been using certain drugs. If the patient hasn't had enough sleep. If the patient has had a recent infection . . . ." Phillips T. 121. Indeed, "exposure to the sun can do this as well." *Id.*

73. It is undisputed that many of the tests performed by AAL have no clinical significance whatsoever and would not be performed by a reputable laboratory. For example:

(a) Dr. Phillips testified that the anti-brush border antibody test performed by AAL was totally inappropriate. "No reputable labortaory has measured this, except for research purposes . . . . [I]t has no clinical significance." Phillips T. 17.

(b) Dr. Phillips testified that the antimyelin antibody test performed by AAL "is of absolutely no biological meaning. It's a useless test." Phillips T. 17-18. This test

is of value only if it is used to test "the cerebral spinal fluid that is in the brain . . . . It has no meaning in the peripheral blood." Phillips T. 17. In the present matter, only blood samples were sent to AAL for analysis; not samples of spinal fluid. Phillips T. 18.

(c) Dr. Phillips also testified that the TA-1 test performed by AAL "is not done at most reputable laboratories . . . . [T]his particular antibody is not standardized [and the test] is not done in reputable laboratories which are certified to do these types of tests." Phillips T. 19-20.

(d) Further, Dr. Phillips stated that the PHA and the concanavalin A tests performed by AAL "are considered to be research only. The biological significance is not known." Phillips T. 20-21.

74. It is undisputed that the methodologies utilized by AAL to perform its testing are not scientifically valid. Harbeck T. 76. For example:

(a) AAL does not utilize dose-response curves to determine if they are using the proper type and amount of reagent in preparing the samples for analysis. Instead, "they arbitrarily pick . . . one dilution of reagent . . . ." Phillips T. 28-29. By not having "the dose response curve to illustrate the reactions . . . [the] tests are meaningless." Phillips T. 29.

(b) The AAL reporting of anti-nuclear antibody results merely as positive or negative is improper. Dr. Phillips testified that "depending on the test it's on, you can't simply say positive or negative, because it doesn't have any meaning." Phillips T. 30.

(c) AAL failed to provide any evidence regarding the use of proper control groups for the test results. Therefore, when AAL reports that a test was positive "it's meaningless." Phillips T. 32.

(d) In order to conduct its cell counting tests for T cells, AAL manually counts approximately 100 cells by

using a microscope. This method is out-dated and is not accepted in the scientific community and it is no longer used. Harbeck T. 82; Phillips T. 35. The manual method utilized by AAL is "not done anymore. It's notoriously inaccurate." Phillips T. 35. Instead, all reputable laboratories utilizes fluorescence activated cell sorting (FACS), which counts a minimum of 10,000 cells and has an accuracy of 99 percent. Phillips T. 32-35. There are laboratories in the Philadelphia area which utilize the FACS technology. Phillips T. 36.

(e) AAL does not "have quality control. They don't send their results out to a third party group or take reference standards from a third party group to allow them to assure that they have standard controls." Phillips T. 37.

(f) AAL does not identity the source of the reagents used in its testing. "[A]ny accredited, reputable laboratory would have the source of where you get these reagents. . . . [T]here's no evidence of where these were obtained, nor at what concentration . . . that they were used at." Harbeck T. 77. The source of the human serum used as the reagent is "a critical aspect of these sorts of experiments." Harbeck T. 78.

(g) The written procedures provided by AAL are "totally inadequate." Harbeck T. 79, 84.

(h) The tests performed by AAL need to be done within 24 hours after the blood is drawn. If the test is not conducted within this timeframe, "then there's a real problem with it." Harbeck T. 80. AAL provided no documentation as to when the blood samples were drawn. Harback T. 80-81.

75. The test results reported by AAL for the Plaintiffs' blood samples showed no pattern of similar response and there is no consistency among the results. Phillips T. 39-40.

76. AAL is not accredited by the College of American Pathologists ("CAP"). Harbeck T. 84-85. Accreditation by CAP ensures that the lab is "scrutinized by an on-site visit of peers who look at every aspect of laboratory operations, including quality control, sample acquisition, sample processing, reporting of results, instrument maintenance, external proficiency testing where you share your samples with other laboratories . . . ." Harbeck T. 85. By not undergoing accreditation, AAL avoids this type of scrutiny. Harbeck T. 86.

77. It is undisputed that the testing performed by AAL is not scientifically valid, that the tests are not accepted by the medical or the scientific communities as a means for measuring possible immunological effects of chemical exposure, that the methodologies and procedures utilized by AAL in performing the tests are not accepted in the scientific or medical community, and that the tests are of no clinical significance and would not be performed by a reputable laboratory. Phillips T. 17-21, 27, 41; Harbeck T. 76, 79, 84.

78. The AAL data is not data of the type reasonably relied upon in the medical profession. Fink T. 36; Weitekamp T. 67-68, 71; Phillips T. 17-21, 27, 35, 41; Harbeck T. 76, 79, 84. These experts explain that no competent expert in the fields of immunology, toxicology, or internal medicine would rely upon one set of immunological data—particularly data that are, as discussed above, totally unreliable—to offer the type of far-reaching conclusions that Dr. Sherman does. They point out that these immunological tests are not and cannot be relied upon by experts in the field to demonstrate "cellular damage," as Dr. Sherman claims. Fink T. 35-36, 38-39. And, they note that many of the specific immune parameters that Dr. Sherman insists are indicative of disease are in fact regularly present in individuals with no clinical manifestations of disease whatsoever. Phillips T. 10-11. They unequivocally attest that no expert in the field would

ever rely on these tests to diagnose an increased risk of cancer, as Dr. Sherman does. Thus, Dr. Sherman uses unreliable test results in a manner not recognized as acceptable by experts in any field of clinical medicine.

79. Dr. S. Michael Phillips, who is a professor of medicine at the University of Pennsylvania in the Allergy and Immunology Section and board-certified in internal medicine, allergy and immunology, testified that these tests "would not have been performed by a reputable immunologist for medical reasons." Phillips T. 17-21. Dr. Phillips also points out that the tests are unjustified, inappropriate, and invalid; that they mislead less sophisticated physicians and patients into believing that nonexistent immunologic abnormalities actually exist; and that no credibility should be accorded to such misleading and potentially dangerous findings. Phillips T. 10-11.

80. Drs. Fink, Phillips and Harbeck also have reviewed the protocol followed by AAL in performing the immune tests on which Dr. Sherman so heavily relies. They find serious flaws in the lab's method, and conclude that the results obtained from the "Chemical Injury Kit" are totally unreliable. Fink T. 44, 46; Harbeck T. 76; Phillips T. 41. For example, the lab often did not have control data, and several of the immune tests were not titered, making it scientifically impossible to rely on or determine the significance of the test results. Fink T. 44-45; Phillips T. 28-29.

CONCLUSIONS OF LAW

1. The hearings held by this Court on Defendants' motion *in limine* on July 28, 29, 30, 31 and August 3, 1992 have produced a record sufficient to evaluate Dr. Sherman's testimony under Rules 702, 703, and 403. In particular, the Court has made "a factual inquiry and finding as to what data experts in the field find reliable" (Rule 703) and created "a developed record and specific findings on reliabiltiy issues" (Rule 702). *In re Japanese Electronic Products Antitrust Litigation,* 723 F.2d 238,

277 (3d Cir. 1983); *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 859 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991).

2. Rule 702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702.

3. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert." *DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). If an expert is unqualified to offer the opinions she proposes, her testimony must be excluded from the trial. *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 272 (3d Cir. 1991); *see also Tokio Marine and Fire Ins. Co. v. Grove Manufacturing Co.*, 958 F.2d 1169, 1173-75 (1st Cir. 1992) (upholding exclusion of expert who was a "professional witness" and whose "opinions are available to the highest bidder as unqualified under Rule 702".)

4. Although Dr. Sherman received her medical degree in 1964, she did not complete a three-year residency program and has not diagnosed, treated or cared for individuals on an ongoing medical basis for the past 16 years. Findings of Fact ("FF") ¶¶ 1, 2. Since 1976, substantially all of the income Dr. Sherman generates is from her work in cases that involve litigation. She has participated in over 8,000 cases and has given depositions over 800 times. Dr. Sherman could not remember a single instance in which she examined an individual supposedly exposed to PCBs where she concluded that PCBs had not caused adverse health effects. FF ¶ 3. She has not had admitting privileges to any hospital since 1976 and does not maintain an office at which she can examine

patients. FF ¶¶ 4, 5. Dr. Sherman offers herself as an expert in internal medicine and toxicology and admits that she is not an expert in immunology, oncology, neurology, psychiatry, dermatology, epidemiology and exposure assessment. FF ¶ 6. She is not board-certified in any medical discipline. FF ¶ 7. Dr. Sherman contends that she became an expert in toxicology in the 1980s through experience, reading, writing, teaching, evaluating patients and course work. She took no toxicology courses in medical school and her training does not indicate that she is an expert in that discipline. FF ¶ 9. Dr. Jordan Fink, was called by Defendants and his qualifications appear at Factual Findings, paragraph 10. Dr. Fink testified that Dr. Sherman is unqualified to offer expert testimony in the fields of internal medicine for immunology. Dr. Fink recounted numerous errors in basic medical terminology and principles made by Dr. Sherman and concluded that these fundamental errors indicated Dr. Sherman's lack of qualifications. FF ¶ 11. He indicated further that Dr. Sherman's own testimony shows that she does not understand the functioning of the immune system; does not understand the immune tests that she ordered and purported to rely upon and that she is not qualified to interpret those tests. FF ¶ 11.

5. The defense called Dr. Paul Roediger as an expert and his qualifications are set forth in Factual Findings, paragraph 12. He testified that Dr. Sherman is not qualified as an expert in internal medicine, toxicology or immunology. He testified that Dr. Sherman would not receive admitting privileges at Abington Memorial Hospital and that the standards at Abington for granting privileges were similar to those employed in most hospitals in the country. He agreed with Dr. Fink's testimony with reference to Dr. Sherman's ignorance of the basic principles of internal medicine. FF ¶ 13.

6. Defense called Dr. James Leyden whose qualifications appear in the Factual Findings at paragraph 14.

Dr. Leyden testified that Dr. Sherman was not an expert in dermatology and was not qualified to diagnose chloracne or any dermatologic condition. FF ¶ 15. Dr. Morgan was also called by the Defendants and his qualifications appear in the Factual Findings at paragraph 18. Dr. Morgan testiefid that Dr. Sherman "does not have the qualifications that one would normally expect of an internist," and that she was also not qualified in the field of occupational medicine. He also noted that she had not practiced medicine for 16 years and cited several errors in basic anatomy and immunology that Dr. Sherman made in her deposition. FF ¶ 18. Dr. Weitekamp was called as a defense witness and his qualifications appear in the Factual Findings at paragraph 19. He also noted many errors made by Dr. Sherman with regard to basic principles of internal medicine and immunology and that she was unqualified in the fields of internal medicine and immunology. FF ¶ 19.

7. I find on the basis of the foregoing that Dr. Sherman is not qualified to testify as an expert witness at trial and that her testimony must be excluded under Rule 702.

8. In *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), the Court said "Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based on unreliable methodology is unhelpful and therefore excludable."

9. All of the doctors who reviewed Dr. Sherman's testimony found that she failed to follow medically or scientifically reliable methodology in reaching her opinions in this case. *See* as to Dr. Fink, FF ¶ 11; as to Dr. Roediger, FF ¶ 13; as to Dr. Leyden, FF ¶ 15; as to Dr. Harbeck, FF ¶ 17, as to Dr. Morgan, FF ¶ 18; as to Dr. Weitekamp, FF ¶ 19, as to Dr. Phillips, FF ¶ 20. According to these witness who are all highly qualified in their respective fields, she did not order standard laboratory tests to be performed on Plaintiffs; she did not physically examine or take medically histories from most of the

Plaintiffs for whom she offered opinions; and as to the three Plaintiffs she did examine, she did so at the Plaintiffs' attorneys' offices and not in a medical office or hospital.

10. Drs. Fink, Roediger, Weitekamp and Morgan testified that a differential diagnosis—where the physician either rules in or rules out alternative causes for diseases—is the hallmark of internal medicine. According to Dr. Fink considering alternative causes is "the basic practice of internal medicine. That's what the internist does, make a diagnosis by taking the entire picture, outlining what the possibilities [are] and then honing down based on his knowledge and experience and literature that he has read, etc., in making a diagnosis." FF ¶ 54. Dr. Sherman does not follow this procedure, she assigns PCBs as the cause of the disease and does not consider and rule out any alternative causes. *See* FF ¶ 55 for a list of illnesses she attributes to PCBs; *see also* FF ¶ 62 for an example of Dr. Sherman's failure to rule out other causes of disease.

11. A shocking example of Dr. Sherman's methodology is set forth on pages 685 and 686 of her deposition. Bear in mind before you read this that Dr. Leyden, who has been described as one of the four or five most prominent dermatologists in the country, has testified that he can tell the difference between chloracne and common acne at fifty paces. FF ¶¶ 14, 15. I single out this particular testimony not only to illustrate that Dr. Sherman does not know the difference between the two types of acne, but more importantly to illustrate the methodology she used throughout all of her testimony:

Q. Have you ever seen chloracne?

A. Yes.

Q. Could you describe it for me?

A. It looks like your standard so-called teenage acne.

Q. Does it differ in any way from standard teenage acne?

A. Well, see, I'm glad you asked that question because how much of—how much of, quote, standard teenage acne is really chloracne that was never diagnosed correctly. Let's say you are a 15-year old boy living at Paoli, and you come to me because you have got acne on your face. And I say to you, oh, gee, there, Mr. Vardaman—well, I wouldn't call you Mr. Vardaman—you had better stop eating chocolate, and you had better wash your face with this kind of thing. But if I don't know that you lived at Paoli and I don't know that you have been exposed to PCBs, I may just say that you have got ordinary acne. Most of the acne cases have never been tested for PCBs.

Q. So, what is your answer? Can you differentiate chloracne from adolescent acne?

A. Yes.

Q. How do you do that?

A. You take a history.

Q. Is there any way, other than taking a history?

A. Yes.

Q. How?

A. Measure the soil. You measure for PCBs. You measure for dioxins. You measure for furans.

Q. Is there any way by simple looking at the patient and distinguishing between ordinary teenage acne and chloracne?

A. Well, we don't know whether ordinary teenage acne isn't really chloracne. You see, without a history, you don't know.

Could we stop to go to the loo for a minute.

12. I find that Dr. Sherman's failure to consider alternative causes of the Plaintiffs' complaints renders her testimony scientifically unreliable and legally inadmissible.

13. I find that Dr. Sherman's methodology with regard to her recommendation concerning medical screening is equally unreliable in that they do not employ recognized scientific techniques. Weitekamp T. 70-71

14. Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703. Thus, if an expert relies upon facts or data not otherwise admissible and not reasonably relied upon by experts in the relevant field, then the opinion must be excluded. *Japanese Electronics,* 723 F.2d at 277.

15. The testimony of Drs. Fink, Phillips, and Harbeck demonstrates that the data Dr. Sherman relies upon, mainly the immunological test results from a "Chemical Injury Kit" administered by an uncredited lab, were not of the type reasonably relied upon by experts in any field of medicine to form a medical opinion. As Dr. Fink's states, "Dr. Sherman's use and interpretation of these tests reflects a general deficit in her—fundamental understanding of medicine and immunology." Fink T. 37-38. *See also* Phillips T. 10 (where he states that the immunological tests are not important or meaningful in the clinical evaluation of a patient and "they probably would be more misleading and dangerous than helpful").

16. I find that Drs. Fink and Phillips are well qualified to testify as to what data experts in their fields rely upon to reach medical opinions.

17. Plaintiffs have presented no expert to testify that immune data such as that ordered by Dr. Sherman are relied upon by experts in the fields. Defendants' evidence is undisputed on this point.

18. After considering the testimony, I conclude that the AAL data is not of the type reasonably relied upon by experts in those fields to reach the type of conclusion reached by Dr. Sherman. For this reason, I find Dr. Sherman's testimony must be excluded under Rule 703.

19. In *United States v. Downing*, 753 F.2d at 1242, the Court stated even if proffered evidence satisfies Rule 702 the district court may decide nevertheless to invoke Rule 403 to exclude the evidence.

20. Rule 403 states: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

21. Although pretrial Rule 403 exclusions are infrequent, when the court has a record complete enough on the point at issue to be considered a virtual surrogate for a trial record, it may exclude the testimony under Rule 403. *Paoli*, 916 F.2d at 859-60.

22. Testimony should be excluded if it would overwhelm, confuse or mislead the jury. *DeLuca*, 911 F.2d at 951; *Downing*, 752 F.2d at 1237.

23. Dr. Sherman's methodology of literally attributing every complaint a party has to PCBs when there is an allegation that the party has been exposed to PCBs would cause the jury to attribute more probative value to her opinion than that to which it would be entitled.

24. Dr. Sherman's practice of simply concluding that PCBs are a cause of a particular complaint and giving no basis for her opinion places an unfair burden upon

the defense to prove that PCBs were in fact not the cause of the complaint. In effect, it requires the defense to perform the differential diagnoses that Dr. Sherman should have done before reaching her conclusion.

25. The dangers of "confusion of the issues, or misleading the jury," are enhanced greatly by the manner in which Dr. Sherman either answers or avoids answering questions on cross-examination. See for example, *Sherman* Dep. 179, where defense counsel attempted to have her answer a question as to whether the author of an article concluded that PCBs caused high blood pressure. See also *Sherman* Dep. 131-43, where defense counsel attempted to get her to state whether John Ingram's PCB level was higher than that of the average for the population in the Philadelphia area among those who had no known exposure to PCBs.

DISCUSSION

I have found that Dr. Sherman is not qualified as an expert under Rule 702. In so doing, I have considered the length of time that has passed since she graduated from medical school and completed her one-year rotating internship and the fact that she does not diagnose, treat or care for individuals on an ongoing medical basis. As a matter of fact, she has not done so for the past sixteen years. From 1976 to the present, the only patients that Dr. Sherman has seen have been seen in the context of litigation consultation. Since 1976, substantially all of the income that she generated from her professional activities has come from work in cases that involve litigation. She has given over 800 depositions during that period and in all but two of those cases her testimony has been for the plaintiffs or claimants. Dr. Sherman could remember only a single instance in which she examined an individual allegedly exposed to PCBs where she concluded that PCBs had not caused adverse health effects.

Dr. Sherman has not had admitting privileges to any hospital in the country since 1976 and has not office at which she examines patients. Although Dr. Sherman offers herself as an expert in internal medicine and toxicology, she took no courses in toxicology in medical school and her subsequent training does not indicate that she has gained expertise since that time. She has never been board-certified in any medical discipline including internal medicine.

Dr. Sherman claims to have been involved in research of toxicologic problems since she concluded her clinical practice. This would appear to be library research of current literature on the subject. I did not observe anything in Dr. Sherman's testimony that indicted this so-called research was of a serious nature.

The expert witnesses called by the Defendants were impressive by reason of their education, their experiences and training since their formal years of education and the positions that they have held and presently hold in the medical field. Dr. Fink, for example, testified that Dr. Sherman is not qualified, that she does not employ the basic principles of internal medicine and that she demonstrates a fundamental lack of knowledge. He indicated that she is absolutely not competent to analyze the immune tests that she ordered and that she doesn't know basic immunology. Dr. Roediger agreed with that analysis and in addition stated that she would not be eligible for staff privileges at Abington Memorail Hospital. Dr. Roediger supervises the quality control aspects of the medical care at Abington Memorial Hospital and is in charge of 54 internists. He indicated that he has been reviewing the work of internists and doctors at the hospital for 20 to 30 years.

Dr. Leyden indicates that she is not qualified in the field of dermatology and was severely critical of her methodology and her lack of knowledge with reference

to acne. Dr. Weitekamp who is Chief of Internal Medicine at the Hershey Medical Center stated that Dr. Sherman is not qualified and that she displayed a basic lack of knowledge.

For all of these reasons, I find that Dr. Sherman is not qualified to testify as an expert in this case.

I therefore issue the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams, v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of Oct., 1992, based upon the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that Defendants' Motion *In Limine* to Exclude the Opinion Testimony of Janette D. Sherman, M.D. is GRANTED, and it is further ORDERED that Defendants' Motion *In Limine* to Exclude All Testimony Concerning Tests Performed at Antibody Assay Laboratories, Inc. is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
Judge

APPENDIX III-B

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master Dockets No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *SEPTA, et al.*	No. 86-2235
John Ingram, et al. v. *SEPTA, et al.*	No. 86-7561
Andre Williams v. *SEPTA, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *SEPTA, et al.*	No. 87-5269

MEMORANDUM

R.F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE TESTIMONY OF IAN C. T. NISBET, Ph.D.

This is a toxic tort case brought by individuals who maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") from having either worked in or lived adjacent to the Paoli Railyard in Paoli, Pennsylvania. PCBs were used for decades in the transformers of the Paoli railcars and were found in elevated levels in the air and soil at and around the Paoli Railyard. Plaintiffs filed their complaints beginning in 1986. On November 28, 1988, this Court granted Defendants' Joint Motion for Summary Judgment against all Plaintiffs on their personal

injury claims. On September 20, 1990, the Third Circuit reversed the award of summary judgment in favor of Defendants and remanded the case to this Court for further proceedings consistent with its opinion. In accordance with the Third Circuit opinion, this Court held hearings on July 28, 29, 31 and August 3 and 7, 1992 eliciting testimony and argument on the numerous motions *in limine* and dispositive motions filed in this action.

Defendants filed this Motion *In Limine* to Exclude the Testimony of Ian C.T. Nisbet, Ph.D. Plaintiffs offer Ian C.T. Nisbet, Ph.D. ("Dr. Nisbet") as an expert in assessing the exposure of Plaintiffs to PCBs. Defendants argue that the testimony of Dr. Nisbet must be excluded since his opinions are based upon an unreliable methodology, erroneous factual assumptions and data not reasonably relied upon by experts in the relevant fields of science. Defendants argue that Nisbet's testimony should be excluded pursuant to Rules 702, 703 and 403 of the Federal Rules of Evidence.

A hearing on this motion was conducted on July 29 and 30, 1992. All parties were permitted to present witnesses and exhibits in support of or in response to this motion. Dr. Nisbet opines that several of the Plaintiffs were exposed to sufficient levels of PCBs to lead to the conclusion that they would suffer adverse health effects as a result of their exposure to PCBs. Upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Ian C.T. Nisbet, Ph.D., all response thereto, the hearing and deposition testimony presented to this Court, and all exhibits admitted into evidence at the hearing, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Defendants presented the testimony of John Whysner, M.D., Ph.D. ("Dr. Whysner") in support of its motion *in limine* to exclude the testimony of Dr. Nisbet.

July 30, 1992 Hearing Testimony of Dr. Whysner ("Whysner T."). Defendants also introduced into evidence at the hearing Dr. Whysner's curriculum vitae (Defendants' *in limine* Exhibit 20), Dr. Whysner's affidavit (Defendants' *in limine* Exhibits 21), and the sworn deposition testimony of Dr. Nisbet (Defendants' *in limine* Exhibit 22).

2. Dr. Whysner, a physician and scientist, received his M.D. and his Ph.D. in Biochemistry from the University of Southern California School of Medicine in 1970. Whysner T. 5. Dr. Whysner's formal training in toxicology began when he was an undergraduate at the University of Southern California where he researched biological toxins. *Id.* at 6.

3. After receiving his M.D. and Ph.D., Dr. Whysner served as a pediatric intern for one year and spent two years as a post-doctorate fellow at the National Institute of Child Health and Human Development. *Id.* at 8.

4. In the early 1970s, Dr. Whysner supervised various toxicology studies for the executive office of the President. The studies involved the investigation of new pharmaceuticals for the treatment of drug abuse and the toxicity of certain illegal substances used in drug abuse. *Id.* at 6.

5. In the mid-to-late 1970s, Dr. Whysner was hired by the Center for Disease Control, the Department of Housing and Urban Development, and the National Bureau of Standards to investigate the toxicology of lead-based paint. *Id.* He later worked for the United States government under contract with the National Institute on Drug Abuse doing pharmaceutical research. Under this contract, he served as a toxicologist in terms of evaluating adverse drug reactions for the various pharmaceuticals tested. *Id.* at 6-7.

6. In the 1980s, Dr. Whysner worked in the area of occupational and environmental health for Washington Occupational Health Associates, Inc. where he investi-

gated the toxicological aspects of various occupational and environmental exposures. *Id.* at 7.

7. Presently, Dr. Whysner splits his time between the American Health Foundation, a non-profit research organization, and Washington Occupational Health Associates, Inc. At the American Health Foundation, he is in the department of pathology and toxicology and is currently in charge of an international expert panel that is looking into certain issues regarding the mechanism of cancer and cancer risk assessment. He also serves as Executive Secretary for the environmental health and safety council. *Id.*

8. Dr. Whysner's experience with exposure assessment includes assessing the exposure of children to lead from eating paint and performing exposure assessments on various environmental and occupational problems specifically PCBs, dioxins, dibenzofurans, polyaromatic hydrocarbons, and many other metallic elements and compounds. *Id.* at 8.

9. Dr. Whysner was offered by Defendants at the *in limine* hearing as an expert in toxicology and exposure assessment. *Id.* Plaintiffs did not challenge Dr. Whysner's qualifications.

10. Dr. Whysner reviewed the following: the deposition testimony of Dr. Nisbet; data concerning tests of Plainitffs' PCB blood levels performed by American Medical Laboratories, Inc.; data comparing the reliability of American Medical Laboratories, Inc. to other labs; the 1987 federal study undertaken by the Agency for Toxic Substances and Disease Registry of the Paoli residents; other studies of persons living near sites containing PCBs; and literature related to background PCB exposure levels. *Id.* at 9.

11. At the *in limine* hearing, Plaintiffs presented the testimony of Dr. Nisbet. July 30, 1992 Hearing Testimony of Dr. Nisbet ("Nisbet T."). Plaintiffs also intro-

duced into evidence at the hearing Dr. Nisbet's curriculum vitate (Nisbet *in limine* Exhibit P-1), Dr. Nisbet's handwritten notes regarding his back-calculations (Nisbet *in limine* Exhibit P-2), and an article titled "Methylmercury Poisoning in Iraq" (Nisbet *in limine* Exhibit P-3).

12. Dr. Nisbet received his bachelor's degree in 1954 from the University of Cambridge in England. He received his master's degree and Ph.D. degree in 1958 from the University of Cambridge. Dr. Nisbet's Ph.D. was in Physics with a specialization in fluid mechanics. Nisbet T. 59.

13. Dr. Nisbet did post-doctoral work for two years at Cornell University and Massachusetts Institute of Technology. He also did three years of post-doctoral work at the University of Cambridge. *Id.* at 59-60.

14. After completing his education in 1963, Dr. Nisbet spent five years teaching at the University of Malaya. Dr. Nisbet came to the United States in 1968. Since 1968, he has worked exclusively in the environmental sciences focusing on the behavior of chemicals and the effects of chemicals on the environment. *Id.* at 60.

15. In the early 1970s, Dr. Nisbet applied his mathematical knowledge to the modeling of the way chemicals move in the environment which led to what is now called "exposure assessment." In the mid-1970s, his work expanded into what is now called "risk assessment" which is the calculation of the likely effects of toxic chemicals on the environment. *Id.* at 60-61.

16. Since the mid-1970s, Dr. Nisbet's work has been almost exclusively in the area of risk assessment through tracking the way chemicals move in the environment and assessing exposure to the chemicals using toxicological and epidemiological information to assess risks. *Id.* at 61.

17. In 1975, the EPA commissioned Dr. Nisbet to produce a "criteria document" which was designed to summarize and analyze the considerable body of human and animal studies about PCBs.

18. The Electrical Power Research Institute ("EPRI") commissioned Dr. Nisbet's organization to do a review of PCB literature. Whysner T. 55-56. Drs. Whysner and Chase, two of Defendants' experts in this case, worked as subcontractors to Dr. Nisbet's group.

19. In 1991, Dr. Nisbet was selected by the Agency for Toxic Substances and Disease Registry ("ATSDR") as one of three peer reviewers for the draft of ATSDR's toxicological profile on PCBs. Nisbet T. 109.

20. Over the past twelve months, approximately 40% of Dr. Nisbet's time was spent working on cases that were in litigation. *Id.* at 107. Approximately 60% of Dr. Nisbet's income was derived from litigation-related activities over the past twelve months. *Id.* at 108.

21. Dr. Nisbet considers himself an expert in analytical chemistry in the limited area of reading and interpreting gas chromatograms of chlorinated hydrocarbons including PCBs. *Id.* at 108-09. However, when he submitted comments regarding his review of the ATSDR draft in 1991, Dr. Nisbet stated that he was not a specialist in analytical chemistry. *Id.* at 111.

22. There are two main methods used in assessing exposure to PCBs or any other chemical. The first method involves the measuring of a particular chemical in blood or urine samples through a regular laboratory test. Whysner T. 9-10. The laboratory provides a reference range along with the lab results which is the normal range for people who have been tested and do not have any unusual exposure to the chemicals. *Id.* at 10. The other method is called "exposure assessment" and is utilized for chemicals in which there are no good measurements in the blood. This method involves looking at the amounts of the particular chemicals in the environment, using a modeling system to develop hypothetical ways in which people could become exposed to those chemicals and deriving the amount of the chemicals that could be absorbed into the body. *Id.* These types of calculations are

usually done for regulatory purposes and do not assess what the actual levels of exposures are but assess the upper bounds of potential future exposures. *Id.* at 10, 34-35.

23. Dr. Whysner testified that Dr. Nisbet did not follow either of these methodologies. "He did not use the method directly of assessing in the blood but relied upon recalculation of laboratory results that had been obtained." *Id.* at 10-11. Dr. Nisbet did not perform an exposure assessment in this case nor did he specifically quantify the intake of PCBs experienced by any of the Plaintiffs. *Id.* at 11. Moreover, Dr. Nisbet did not perform a risk assessment in this case. *Id.*

24. In assessing Plaintiffs' exposure to PCBs, Dr. Nisbet took into account the history of use of PCBs at the Paoli Rail Yard and his own knowledge of the history of use and disposal of PCBs in the United States and other similar environments since 1970. Nisbet T. 82.

25. Dr. Nisbet concluded that Plaintiffs' exposure to PCBs was greatest before 1986 and "probably greatest in the early 1980s or 1970s." *Id.* at 85. However, he stated that "quantitatively, I don't know how the exposure changed in the years prior to 1986." *Id.* at 86. Dr. Nisbet based his conclusion that exposure was greatest prior to 1986 on the following: Monsanto halted PCB sales to customers who employed PCBs in other than so-called "closed systems" in 1971; Monsanto began warning its customers who warned their customers about the potential harms associated with PCB contamination in the early to mid-1970s; the 1976 passage of the Toxic Substances Control Act ("TSCA"); the promulgation of stringent TSCA regulations governing disposal of PCBs; improved "housekeeping" measures taken by the defendant railroads including the 1980 adoption of spill prevention control plans applicable to the Paoli Railyard; and the mid-1980s emergency measure taken by EPA to reduce water run-off from the Paoli Railyard to Plaintiffs' homes. *Id.* at 82-86; Nisbet Dep. 68-69.

26. In forming his conclusions, Dr. Nisbet also took into account Plaintiffs' own statements regarding how they used the environment, and the fact that Plaintiffs learned about the contamination in 1986 and undertook steps to reduce their contact with PCBs. Nisbet T. 82-83.

27. Dr. Nisbet reviewed Plaintiffs' files which included medical records, employment records for the employees, responses to interrogatories, and responses to questionnaires from some of the Plaintiffs. Nisbet Dep. 24.

28. Dr. Nisbet also reviewed information on the levels of PCBs in Plaintiffs' blood including some chromatograms and he reviewed various documents pertaining to the soil contamination at the Paoli Railyard and surrounding area. *Id.* at 25, 29, 35.

29. Dr. Nisbet admitted that he had no information about: any Plaintiff's exposure to PCBs at any time prior to 1986; the levels of PCBs in the soil of the Paoli neighborhood throughout 1950s, 1960s, and 1970s; the amount of PCBs used or disposed at the Paoli Railyard; the amount of surface run-off from the Yard at any time; the quantity of PCBs in the surface run-off; or the amount of rainfall in the Paoli area for any time period. *Id.* at 49, 69, 139, 144; Nisbet T. 86, 120-22.

30. Based upon all the information that he reviewed, Dr. Nisbet formed the opinion that several of the Plaintiffs "were sufficiently exposed [to PCBs from the Paoli Railyard] . . . to lead to the expectation that they would suffer adverse health effects as a result of th[eir] exposure." March 16, 1992 Report of Dr. Nisbet at 2, 6 (Attached as Exhibit 12 to Defendants' *in limine* Exhibit 22) ("Nisbet Report").

31. Dr. Nisbet expressed his opinion regarding the following six Plaintiffs: Priscillia Burrell; Amber Burrell; Bessie Cunningham; Matthew Cunningham; Patricia Ingram; and Andre Williams. Nisbet Dep. 474-75.

32. Dr. Nisbet did not quantify any of Plaintiffs' intake of PCBs nor does he believe it can be done. Nisbet T. 120. Dr. Nisbet did not quantify the intake of furans or dioxins by any of Plaintiffs. "I have not made any attempt . . . to make a formal calculation of exposure . . . ." Dr. Nisbet maintains that he does not have enough information to make any such calculations. *Id.* He stated that "it's not possible to make a quantitative estimate of the way in which the Plaintiffs' exposure varied during the 1970s and 1980s." *Id.* at 86. Dr. Nisbet did not at any time request that Plaintiffs be tested for the presence of dioxins, furans or tetraphenyls in their blood or fat tissue. *Id.* at 143-44.

33. Dr. Nisbet has never performed PCB analyses on human blood samples or human tissue samples. *Id.* at 111.

34. Although Dr. Nisbet claims to be an expert in exposure assessment of toxic chemicals, Dr. Nisbet has had no formal training in toxicology or epidemiology. *Id.* at 61, 144.

35. Various Plaintiffs in this case had their blood tested for PCBs in 1986 and 1987 by American Medical Laboratories, Inc. ("AML") and National Medical Services ("NMS"). Whysner T. 11.

36. In 1988, Dr. Nisbet explicitly adopted the AML results when he stated in an affidavit to this Court that "I have reviewed data on PCB levels . . . generated by American Medical Laboratories, Inc. (AML) For 16 of the plaintiffs, the data reported by AML indicate[s] substantial exposure to PCBs . . . ." Affidavit of Dr. Nisbet dated August 16, 1988 at 10 (attached as Exhibit 2 to Defendants' *in limine* Exhibit 22) ("Nisbet Aff."). Dr. Nisbet never questioned the reliability of the AML results in his 1988 affidavit. Nisbet T. 113-14.

37. However, at his deposition in 1992, Dr. Nisbet stated that he no longer considered the AML results to be reliable. Nisbet Dep. 108-09.

38. One basis for this conclusion is Dr. Nisbet's comparson of results from AML and Michigan State Laboratory obtained on the same three samples ("split samples") in March of 1986. Dr. Nisbet testified that AML's reported results were approximately two and a half to three times lower than Michigan State Laboratory's results. *Id.* at 158-60; Nisbet T. 80. During his deposition, he stated that he considered the Michigan State Laboratory to be more reliable than AML or that it was more reliable than AML at that time because he had independent knowledge of the Michigan State Laboratory. Nisbet Dep. 108. Based upon this belief and the 1986 lack of comparison between AML's results and the Michigan State Laboratory's results, Dr. Nisbet believed that the numbers reported by AML were "wrong, almost certainly wrong by a substantial factor" and that AML's results would generally be approximately two and a half to three times too low. *Id.* at 158, 164-68.

39. Applying this theory, Dr. Nisbet recalculated the results reported by AML in August of 1987 of Plaintiffs' PCB blood levels by multiplying these results by a factor of approximately two and a half to three yielding "recalibrated estimates." *Id.* at 159, 165 (emphasis added). Dr. Nisbet characterized his calculations at his deposition as follows:

> Q. And the method you used to do this recalculation is what?
>
> A. Simple multiplication.
>
> * * *
>
> Q. You used it only to give you some rough estimate, correct?
>
> A. That's correct.
>
> Q. Okay. But you think, as a scientist, that's an acceptable way to proceed, correct?
>
> A. If that's the only information you have, that's certainly acceptable.

Id. at 159, 178.

40. Dr. Whysner stated that there are a variety of reasons that could account for the difference in the 1986 split sample results of AML and Michigan State Laboratory. Whysner T. 14. One possible explanation is that something happened to the sample in transit to the laboratory or while the sample was stored. Another possibility is that one of the laboratories on that particular day was reading values on the high side and the other laboratory was reading on the low side. *Id.* at 14-15.

41. Dr. Whysner testified that it is common practice in the scientific community to contact the laboratory and request specific data regarding a sample testing if you think there are problems with the split sample results. *Id.* at 16-17. Dr. Whysner testified that "when I saw the deposition and the letter that Dr. Nisbet was relying upon, I called AML and asked them for any information they had about split samples or proficiency testing and I received it within a couple days." *Id.* at 16. Dr. Nisbet did not request this information from AML.

42. After seeing the data that Dr. Whysner referred to in his testimony, Dr. Nisbet admitted that the information showed better agreement between AML and the Michigan State Laboratory but he stated that the information showed disagreements between both of these labs and another lab. Nisbet T. 80. Dr. Nisbet went on to state that in order to place great weight on any of the blood sample results done by the various labs in 1986 or 1987, he would have to further review the information. *Id.*

43. Dr. Nisbet maintained that Plaintiffs' 1987 AML results are understated and unreliable for the following reasons: AML used an obsolete, low quality method; back-up data in the form of standards or quality control information, spikes, blanks, and surrogates was missing and unreviewable; a letter dated October 7, 1986 from SEPTA's counsel which stated in part that he lacked confidence in the PCB blood level results obtained from various labs in 1986 which included AML; lack of simi-

larity between the sample chromatogram and the chromatogram from the aroclor standard; some samples were not analyzed for approximately a month after they were collected; lack of information regarding how the samples were stored during that month in order to ascertain whether samples were kept under appropriate storage conditions; Plaintiffs' PCB blood levels as measured by AML in 1987 were comparable to the results recorded by Eco Logic in 1992 and Dr. Nisbet believed that the PCB blood levels should have dramatically decreased during this time period due to the half-lives; AML analyzed plasma not serum which Dr. Nisbet believes understates PCB levels; and the fact that the three split samples tested by AML in March of 1986 showed disagreement with the results from the Michigan State Laboratory. *Id.* at 73, 75-80, 101-02; Nisbet Dep. 106-07.

44. AML used the packed column method in analyzing Plaintiffs' blood samples in 1987. Nisbet T. 71.

45. There are two methods of analyzing PCBs. The first method is the capillary column method which separates the components of a PCB mixture. There may be 60 to 80 different PCB components which are called "congeners" in a human blood sample or an environmental PCB mixture. *Id.* at 69. The second method of analyzing PCBs is the packed column method. This is an older method which separates the congeners out into groups not the individual congeners. *Id.* at 70.

46. Dr. Nisbet testified that the capillary column method produces more information about the specific PCB congeners however more interpretation is needed. He stated that the packed column method is simpler, older, less expensive and a better known technique. *Id.* at 70, 72.

47. Dr. Nisbet testified that the AML data was unreliable because "the samples were not analyzed for more than a month after they were collected, as shown by the dates on the reports." *Id.* at 79. However, Dr. Nisbet

admitted at the hearing that the interval between the time the sample was collected and the time the results were repored was approximately two weeks. *Id.* at 117-18. Furthermore, the interval between the collection of blood samples and the 1992 report by ELI Eco Logic Laboratories, Inc. upon which Dr. Nisbet relied was in fact more than two months. *Id.* at 119.

48. Dr. Nesbit stated that the AML results were unreliable due to a potential problem that could exist regarding loss of changes in the blood samples during storage since he did not know "whether they were kept under appropriate storage conditions." *Id.* at 79. However, he admitted that he had no information that the 1987 AML samples were actually stored improperly. *Id.* at 119.

49. Another problem that Dr. Nisbet had with the 1987 AML results was that back-up data in the form of standards or quality control information was missing and unreviewable. He testified that he asked Plaintiffs' attorneys in 1990 or 1991 if the quality control data regarding the 1987 AML results could be obtained and was told that it did not exist. However, Dr. Nisbet conceded that he never requested the quality control data from the laboratory since he felt that labs generally don't keep that kind of information years after the tests. *Id.* at 115, 118; Nisbet Dep. 624.

50. This information was in fact available. Defendants obtained AML's back-up information regarding the 1987 blood results and supporting documentation and submitted it into evidence at the *in limine* hearing. Defendants' *in limine* Exhibit AML-1. This information included the following: AML's reports; lab certification documents; a description of AML's analytical method and its laboratory protocol for PCBs; redacted copies of the lab's logbook; chain-of-custody records for Plaintiffs' blood samples which set forth the circumstances of the shipment and handling of those samples; laboratory worksheets;

laboratory comparison data; descriptions of the credentials of AML laboratory analysts; and raw back-up data and instrument output for the samples, laboratory blanks, spiked samples, and standa ds. Defendants' *in limine* Exhibit AML-1. Dr. Nisbet did not review this information to supplement his earlier testimony.

51. Dr. Nisbet concluded that the error he believed existed in the March of 1986 AML results was still present at the laboratory in August of 1987. However, he admitted that the difference could have been greater or less than two and a half to three times by August of 1987. Nisbet Dep. 167-68. Furthermore, Dr. Nisbet could not identify the specific basis for his belief that AML's methods and procedures of analyzing PCBs in blood in August of 1987 were the same as in March of 1986. *Id.* at 168. Dr. Nisbet stated that he discussed this issue with Dr. Simon who was in charge of AML until some time around early 1986. However, Dr. Nisbet could not recollect much about his discussions with Dr. Simon. Mr. Vardaman, counsel for Defendants, asked Dr. Nisbet the following questions at his deposition:

> Q. I want to know, sir, did you have a discussion with Dr. Simon and he told you that the methodology that was being used in August of 1986, August of 1987, was the same as that was used in March of 1986?
>
> A. I'm sure I didn't discuss that specific month, but I recall having a discussion with Dr. Simon about the lab, and I feel confident that if there had been a change in methodology, he would have told me about that and placed a lot of weight on it.
>
> Q. Did you ask him?
>
> A. I don't remember.

Id. at 168-69.

52. Dr. Whysner stated that if "Dr. Nisbet had concerns about the reliability of the results reported by AML,

or any other laboratory, he could, and should, have requested inter-laboratory vertification data from the EPA and the laboratory." Affidavit of Dr. Whysner dated June 25, 1992 at 4 ("Whysner Aff."). Moreover, Dr. Whysner testified that there were other split sample tests and proficiency tests that were performed between March of 1986 and August of 1987 by AML. Whysner T. 15. In split sample testing, laboratories share samples and compare results. Proficiency testing involves the sending of a known sample to a laboratory and the laboratory reports the results. *Id.* Dr. Whysner testified regarding the availability of inter-laboratory comparison data that existed after March of 1986 which would have enabled Nisbet to confirm the reliabiltiy of the 1987 AML blood tests. First, in December of 1986, AML participated in the EPA proficiency testing program. As part of this program, EPA sent spiked samples to certain laboratories to determine the laboratories' accuracy in detecting known analytes. AML produced acceptable results in the EPA proficiency test. Second, in October of 1987, thirteen split samples taken from a group of Paoli Railyard workers were sent to both AML and Michigan State Laboratory and the reported results were very comparable for the two labs. Third, inter-laboratory exchanges of split samples in different cases between AML and Michigan State Laboratory in 1987 and again in 1989 demonstrated excellent comparability in PCB test results between the two labs. Fourth, Washington Occupational Health Associates, Inc. conducted its own proficiency testing beginning in 1986 which continued through 1992. As part of this testing, over 30 blood samples spiked with PCBs were sent to AML. The results of AML in this testing were almost identical to the spiked standard blood. The average result was only 5% higher than spiked samples. *Id.* at 15-16; Whysner Aff. 4-6.

53. In performing his recalculations of the 1987 AML results, Dr. Nisbet did not consider or refer to this inter-laboratory comparison data or the proficiency tests. Whysner T. 17.

54. Dr. Whysner testified that the 1987 AML results were very reliable. *Id.* He stated that it is not scientifically valid to take results obtained in 1986 from three split samples and use them to recalculate blood sample results obtained in 1987 as Dr. Nisbet has done in this case. *Id.* at 17-18. Dr. Whysner testified that as follows:

> I mean to take three samples, comparison samples between two laboratories that were done a year and a half before, and then essentially recalculate samples a year and a half later, is not proper. And there are many transient things [that] can happen in the laboratory at any particular time, and we have very good information regarding the comparability of AML's results with other laboratories within 1987, and in fact, very close to the time that AML took the plaintiffs blood or analyzed the plaintiff's blood.

Id. at 18-19. In all the years Dr. Whysner has been doing exposure assessments, he has never seen an expert use results from three split samples to recalculate results obtained from the same lab a year and half later. *Id.* at 19.

55. In addition to disputing the accuracy of the blood levels reported by AML, Dr. Nisbet also had a problem with the 5 to 30 parts per billion reference range used by AML in 1987 for normal/background exposure level of general population to PCBs. Nisbet T. 96. Dr. Nisbet stated that "the chart shows the same normal range of up to 30 parts per billion all the way from 1950 to 1990, and that's completely at variance of what we know about history of use, disposal, exposure of the general population to PCBs and the blood and fat levels." *Id.*

56. Dr. Whysner testified that the background levels used by AML were based upon over 15 studies which were reported in the literature and reports by various governmental agencies. These background levels represent levels of unexposed persons or persons without any known exposure to PCBs. Whysner T. 19.

57. Dr. Nisbet lowered the general population background PCB levels through the use of results obtained by the EPA in its National Human Adipose Tissue Survey ("NHATS"). Nisbet T. 96-99. NHATS was a study done by the EPA between 1970 and 1983 which analyzed fat samples not blood samples for the presence of PCBs in the general population. *Id.* at 97. NHATS measured the levels of PCBs in the fat samples in parts per million not parts per billion. *Id.* at 98.

58. Dr. Nisbet testified that NHATS showed a continuous and significant decrease in the number of individuals who had levels of PCBs greater than one between 1970 and 1983. *Id.* at 98-99. "A decrease is what you would expect, because levels in the human environment, particularly in human food have declined, which is documented." *Id.* at 99. Dr. Whysner testified that NHATS only reported the PCB fat levels in ranges because the agency did not believe that the data was accurate enough or reliable enough to come up with average levels in the fat tissue. Whysner T. 20.

59. Dr. Nisbet used the NHATS fat data to estimate the total amount of PCBs in the blood of the average person in the United States. Nisbet T. 142; Whysner T. 20-22. "He uses a calculation to estimate a lower level of background blood level using a partitioning coefficient which is a ratio of the amount of PCBs in the blood and amount of PCBs in the fat." Whysner 20-21. Dr. Whysner stated that he has never seen such a use of the NHATS fat data by experts in the field. *Id.* at 21. "I haven't seen it done to calculate blood levels for PCBs based upon fat levels in terms of trying to derive background levels before." *Id.* at 51.

60. The results of the 1987 AML blood tests which Plaintiffs ordered showed that Plaintiffs' PCB blood levels fell within the general population background PCB levels reported by the laboratory. *Id.* at 12, 21.

61. In essence, Dr. Nisbet takes two levels that are almost the same, Plaintiffs' 1987 PCB blood levels and the reported background levels, and recalculates Plaintiffs' PCB levels much higher and the background levels much lower. The result of these recalculations establishes a difference between the two levels. *Id.* at 21-22. Dr. Whysner characterized Dr. Nisbet's recalculations as "manipulating the data." *Id.* at 22.

62. Dr. Whysner stated that the November of 1987 ATSDR study of the Paoli residents found that there was no evidence of unusual exposure or uptake of PCBs in the Paoli residents. *Id.* at 29. The ATSDR study looked at PCB blood levels of people who had soil levels above 150 parts per million versus people who had soil levels below that level and found the blood levels to be virtually identical. *Id.* at 29, 42. The laboratory that analyzed the blood samples for the ATSDR study was the Center for Disease Control which is a United States government laboratory. Dr. Whysner stated that it was a very reputable laboratory. *Id.* at 56. In addition, Dr. Whysner testified that he analyzed the soil levels and bloods levels of Paoli residents who were nonoccupationally exposed and found no correlation between the soil levels in their residential yards and their blood levels. *Id.* at 42, 44. Furthermore, the AML blood tests and the ATSDR study are consistent with results of other governmental studies of persons living near sites containing PCBs that show no evidence of unusual exposure to PCBs. *Id.* at 30.

63. In 1992, six Plaintiffs' PCB blood levels were tested by ELI Eco Logic Laboratories, Inc. ("Eco Logic") of Canada. *Id.* at 22. The results of the Eco Logic data were very comparable to the results on the Plaintiffs obtained in 1986 and 1987 from AML and NMS. *Id.* at 22, 40-41. The 1992 blood tests "support the fact that the plaintiffs have exhibited general background levels over that period of time." *Id.* at 41.

64. Nevertheless, Dr. Nisbet again performed recalculations but this time of the Eco Logic data. *Id.*; Nisbet

T. 86. Dr. Nisbet estimated Plaintiffs' PCB blood levels as of 1986 based upon back-calculations of Plaintiffs' 1992 PCB blood levels recorded by Eco Logic. Nisbet T. 86-87, 102.

65. Dr. Nisbet assumed that Plaintiffs had high levels of PCB exposure prior to 1986. *Id.* at 86. Also, he stated that in 1986 the residents, including these Plaintiffs, took measures to reduce their own exposure. Dr. Nisbet testified that he attempted "to estimate to the degree possible, although not very quantitatively, but I attempted to estimate the range of possible magnitudes of [Plaintiffs' PCB] exposure, based on the most reliable set of data, which was the blood measurements taken in 1992." *Id.* at 86-87.

66. Dr. Whysner testified that the literature and studies do not support Dr. Nisbet's assumption of heavy prior PCB exposure by Plaintiffs above the normal background level. Whysner T. 29-30.

67. Dr. Nisbet utilized the 1992 Eco Logic PCB blood levels to perform a back-calculation of the concentration of specific congeners in the six Plaintiffs based upon various assumptions regarding the half-lives of the PCBs and a model for the back-calculation which incorporated different assumptions about the likelihood of continuing exposure from other sources. Nisbet T. 89-90, 124.

68. Dr. Nisbet projected Plaintiffs' possible "range" of PCB exposure as of 1986. Dr. Nisbet stated that the range was wide due to the fact that he projected back six years over several half-lives for a range of Plaintiffs' exposure to PCBs not a single number for the amount of exposure. *Id.* at 100-02.

69. First, in performing his back-calculations, Dr. Nisbet examined the Eco Logic results for the presence of certain congeners of aroclor 1260 in Plaintiffs' blood. Whysner T. 23. He took the values that are shown for these congeners and doubles these values based upon the

recovery rate of PCBs in the surrogate spike sample which was approximately 50%. (Dr. Whysner noted that Eco Logic did not double these values.) Dr. Nisbet used this recovery rate over the matrix spike sample recovery rate which was virtually 100%. (Dr. Nisbet testified that he was not aware of the matrix recoveries of the blood samples spiked with an aroclor mixture when he made his back-calculations. Nisbet T. 91.) Dr. Nisbet then multiplied the doubled congener values by eight based upon his concept of half-lives that one-half of the PCB congener will dissipate from an individual every two years. Next, he multiplied by "another factor in order to estimate the total amount of this aroclor 1260 based upon this one congener number." Finally, Dr. Nisbet divided these numbers by two since he believes that it is a complex mixture and some of the congeners would have been eliminated from the body. Whysner T. 23-27. "The net effect is to multiply [the congener values] by 16, and then divide [these values] by two and come up with a number." *Id.* at 27. Then end result of Dr. Nisbet's back-calculations is that he estimated that Plaintiffs' 1986 PCB blood levels were approximately eight times what their levels were in 1992. *Id.*

70. Dr. Whysner testified that Dr. Nisbet's back-calculation under these circumstances is not a recognized methodology. *Id.* at 31. "I have never seen [back-calculations] used in this kind of situation;" this is unprecedented and not valid. *Id.* As Dr. Whysner observed regarding the use of back-calculations in this context, "you could hypothesize for anybody that [their PCB levels] could have been much higher [than] the background in the past." *Id.* Dr. Whysner went on to state that "the major [problem with Dr. Nisbet's methodology] is that . . . you have to assume the thing that you are trying to prove in the first place." *Id.* at 28. First, Dr. Nisbet must assume that the results from AML and NMS and the ATSDR study are not valid. He also must assume a huge prior exposure and that exposure went way up

and then way down again. Dr. Whysner stated that these are not valid assumptions. *Id.* at 28-29. He testified that there is simply no evidence of such a significant exposure, and it is not scientifically valid for Dr. Nisbet to use back-calculations to prove such a prior exposure. *Id.* at 29-31. Dr. Nisbet's method is completely speculative. *Id.* at 31-32.

71. Dr. Nisbet testified that the Eco Logic data showed significant levels of PCBs in all six of the Plaintiffs that were tested in 1992. Dr. Nisbet stated that:

> [T]he total levels of PCBs adding all congeners together, varied between 6.7 and 27 parts per billion. Those in themselves are significant levels, particularly in 1992. . . . That's a very crude assessment. Adding it all together you lose nearly all of the information. That's what was wrong with the earlier analyses. My primary conclusions were the ones that I drew from the pattern of occurrenec of specific congeners. . . . [T]here were high levels of certain specific congeners that were characteristic of aroclor 1260 and to a lesser extent, some specific congeners that were very characteristic of aroclor 1254.

Nisbet T. 93.

72. In performing his back-calculations, Dr. Nisbet relied upon congeners 180, 194, 201, 205, 206, 138 and 118. Dr. Nisbet stated that he checked the chromatograms and the computer print-out from the confirmatory column to make sure that the congeners appeared on both capillary columns. *Id.* at 127. However, when asked to identify where congeners 180, 205, 206 and 118 appeared on the confirmatory column print-out, Dr. Nisbet failed to do so. *Id.* at 128-30. He later admitted that he tabulated the confirmatory results on his own by using the chromatograms not the computer print-out prepared by Eco Logic from its confirmation. He stated that he did not use Eco Logic's confirmation because he had not seen it at the time he did his own calculations. *Id.* at 129-30.

73. Dr. Nisbet testified that confirmation by the second column (DB17 column) in congener specific analyses is "pretty important, but it's not crucial, because its internal confirmation comes from the patterns of the currents of the different congeners." *Id.* at 126. He stated that we would use results that were unconfirmed by the DB17 column to evaluate PCB levels in humans but he would not place weight on a single congener without some kind of confirmation. *Id.*

74. Dr. Nisbet used alternative values for half-lives when making his calculations of Plaintiffs' 1986 ranges of exposure. The numbers he used were between one and six years for the various half-lives. *Id.* at 102. Dr. Nisbet stated the following reasons for using different half-lives: information on half-lives indicates that in the absence of any continuing exposure, the half-lives for the specific congeners is a little less than one year; he recognized that there may have been some continuing exposure of Plaintiffs, so he concluded that it was likely that the actual rate of depletion of the congeners from their blood would have been less rapid than a half-life of one year; and he used a range of values higher than one year after "spanning the values that have been reported in the literature for total PCBs to indicate the possible range that may have occurred in those people in 1986. And I drew semi-quantitative conclusions from those ranges, not from a single number." *Id.*

75. Dr. Nisbet stated that the Eco Logic results prove past exposure to the materials used at the Paoli Railyard specifically the aroclor 1260 that was used in some of the transformers. He also maintained that the patterns of the different congeners was not the same as that in aroclor 1260 because they had been highly weathered which shows that the main exposure of Plaintiffs to these congeners had taken place some time in the past. *Id.* at 94.

76. Dr. Nisbet further testified that the Eco Logic results showed that the degree of differentiation in some

of the congener specific analyses was greater in Plaintiffs than that reported of the general population. *Id.* at 95. However, Eco Logic failed to provide a reference range for its 1992 results. Eco Logic did not have information regarding the background levels of the various congeners in the general population. *Id.* at 124.

77. Dr. Nisbet stated that he was satisfied with the reliability of the Eco Logic data since he examined Eco Logic's reports, spoke to the principal scientists who supervised the work, Mr. Gierczak, to clarify various points, the protocol/procedure was reliable, the qualitative identification of the chromatograms for the two different capillary columns was good, and the quality assurance in the quality control data was good. *Id.* at 87-88.

78. Dr. Nisbet testified that if he had access to reliable PCB blood tests for Plaintiffs in 1986, then he would choose the results of these tests over his own estimates using back calculations. *Id.* at 138.

79. Dr. Nisbet stated that he did an exposure assessment for Plaintiffs in the very broad sense but not in the narrow sense. *Id.* at 143-44. Dr. Nisbet testified that he did not perform a risk assessment in this case. He did not project forward. *Id.* at 144.

80. Dr. Nisbet stated that his use of half-lives in this way has been used in the context of projecting back to earlier blood levels of drugs or alcohol. *Id.* at 103. "It's used on a limited basis in environmental situations. The question doesn't often arise in environmental situations for extrapolating backwards." *Id.* Dr. Nisbet gave an example of a study conducted by Toxicologists at the University of Rochester and the University of Baghdad. This was a study of a mercury poisoning epidemic in Iraq in the early 1970s. The study projected backwards from the blood levels of mercury observed in the poisoned people some time after they stopped ingesting the contaminated food to what the levels would have been earlier in the blood. *Id.* at 103-04. However, this study was not

used to determine whether there had been in fact exposure or exposure above the background levels since that was already known. This study was a dose response investigation. *Id.* at 134-36. The inter-university report stated that:

> Large errors may result if an average half-time is used to extrapolate mercury concentrations in blood back to the time of consumption of contaminated bread. Analyses of hair samples . . . give a more accurate recapitulation of exposure and therefore will be of much greater importance in epidemiological studies.

Nisbet *in limine* Exhibit P-3 at 234-35.

81. Dr. Nisbet also stated that he performed back-calculations before in a case involving a pest control operator who died of cancer. Dr. Nisbet took the levels of PCBs that were found in the operator's tissues at the time of death and projected them backwards using information regarding half-lives to estimate what the levels would have been in his blood when he was actively using the pesticides. Nisbet T. 125.

82. Dr. Nisbet gave another example of a study that used back calculations called the Ranch Hand study by the Center for Disease Control which researched Agent Orange veterans. *Id.* at 136. However, Dr. Nisbet subsequently admitted that he was not sure if the Ranch Hand study performed back calculations to estimate exposure or if he was referring to a commentary on the study by another scientist. *Id.* at 146.

CONCLUSIONS OF LAW

1. In cases involving proffers of scientific evidence, the Third Circuit stated that "[i]t would appear that the most efficient procedure that the district court can use in making the reliability determination is an *in limine* hearing." *United States v. Downing*, 753 F.2d 1224, 1241 (3d Cir. 1985). The court went on to state that "[i]n

the course of the *in limine* proceeding, the trial court may consider, *inter alia*, offers of proof, affidavits, stipulations, or learned treatises . . . in addition to testimonial or other documentary evidence (and, of course, legal argument)." *Id.*

2. This Court has before it a developed record and specific findings regarding reliability issues. *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 858 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991). This Court has made a factual inquiry and finding as to what data experts in the field find reliable. *In re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238, 277 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986).

3. The hearings held by this Court on July 29 and 30, 1992 relating to Defendants' Motion *In Limine* to Exclude the Testimony of Dr. Nisbet have produced a sufficient record to evaluate Dr. Nisbet's testimony under Federal Rules of Evidence 702 and 703.

4. The district court has broad discretion to admit or exclude expert evidence. The court's action will be sustained unless "manifestly erroneous.' *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962).

5. A district court's decision to exclude the testimony of an expert will be upheld absent an "abuse of discretion." *Knight v. Otis Elevator Co.*, 596 F.2d 84, 87 (3d Cir. 1979).

6. The Federal Rules of Evidence embody a strong preference for admitting evidence that has some potential of assisting the jury. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 956 (3d Cir. 1990).

I. EXCLUSION BASED UPON RULE 702

7. Rule 702 of the Federal Rules of Evidence ("Rule 702") provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

8. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert and is helpful to the trier of fact." *DeLuca*, 911 F.2d at 954 (citations omitted).

9. There is a presumption of helpfulness given to expert testimony under Rule 702. *Japanese Electronic*, 723 F.2d at 279.

10. Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based upon unreliable methodology is unhelpful and thus excludable. *DeLuca*, 911 F.2d at 954.

11. The focus of the Rule 702 inquiry is on the reliability of the methodology employed by the expert in reaching his or her conclusions. *Paoli*, 916 F.2d at 856-57; *Downing*, 753 F.2d at 1238.

12. The Third Circuit in *Downing* established a more flexible approach to the admissibility of "novel" scientific evidence under Rule 702. 753 F.2d at 1237. *Downing* requires a district court to conduct a preliminary inquiry focusing on:

> (1) the soundness and reliability of the process or technique used in generating the evidence,
>
> (2) the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury, and
>
> (3) the proffered connection between the scientific research or test result to be presented, and particular disputed factual issues in the case.

Id.

13. Novel scientific evidence includes scientific evidence that has not been generally accepted or well-recognized in the particular scientific community to which it belongs so as to warrant recognition by judicial notice. *Paoli*, 916 F.2d at 856 n.34; *Downing*, 753 F.2d at 1234, 1237.

14. The reliability inquiry is flexible. The court may examine a variety of factors in addition to scientific evidence in assessing reliability of a particular technique or methodology. *Downing*, 753 F.2d at 1238. For example, the court may examine the expert's technique in relation to more established modes of scientific analysis and the existence of specialized literature dealing with the expert's technique or methodology. "Both of these factors bear on the likelihood that the scientific basis of the new technique has been exposed to critical scientific scrutiny." *Id.* at 1238-39 (citations omitted). Other factors include: the non-judicial uses to which the scientific technique are put; the qualifications of the expert witness; and the frequency with which the methodology or technique leads to erroneous results. *Id.* at 1239.

15. If a reliable methodology was "so altered as to skew the methodology the methodology itself, *Downing* would be the appropriate vehicle for evaluation" but not if the challenged procedure was an application of an accepted methodology. *Paoli*, 916 F.2d at 858 (citing *DeLuca*, 911 F.2d at 955 n.15).

16. After assessing the reliability of an expert's methodology, the court must determine whether admitting the evidence would overwhelm, confuse or mislead the jury. *See DeLuca*, 911 F.2d at 957.

17. "This inquiry focuses on the extent to which probative scientific evidence is capable of being properly utilized by the jury . . . ." *Id.*

18. The touchstone of Rule 702 is the "helpfulness of the expert testimony, *i.e.*, whether it 'will assist the trier

of fact to understand the evidence or to determine a fact in issue.'" *Downing*, 753 F.2d at 1235 (quoting Fed. R. Evid. 702).

19. Helpfulness turns on whether the expert's methodology is sufficiently reliable so that it will aid the jury in reaching accurate conclusions. *DeLuca*, 911 F.2d at 956 (citation omitted).

20. An expert's opinions cannot rely on unsupported factual assumptions. "In order to testify as an expert under Fed. R. Evid. 702, a witness must be sufficiently qualified and expert testimony must be helpful to the fact finder by providing an adequate factual foundation." *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 272 (3d Cir. 1991) (citations omitted).

21. "An opinion based on false assumptions is unhelpful in aiding the jury in its search for the truth, and is likely to mislead and confuse." *Wilkinson v. Rosenthal & Co.*, 712 F. Supp. 474, 479 (E.D. Pa. 1989).

22. Where the record and factual findings demonstrate that the expert used an unreliable scientific mode of analysis and thus obtained "inaccurate results" from this analysis, the court must exclude the proffered testimony pursuant to Federal Rule of Evidence 702. *See Paoli*, 916 F.2d at 857.

23. Defendants in this case argue that the *Downing* test applies to Dr. Nisbet's methodology in recalculating Plaintiffs' 1987 AML results by a correction factor based upon three values obtained in a split sample test in 1986. Dr. Nisbet disputed the reliability of direct measurements of Plaintiffs' 1987 PCB blood levels and formulated his method of estimating those levels. Findings of Fact ("FF") ¶¶ 38, 39, 43. I conclude that this methodology is indeed novel since it was not performed in conformance with any known methodology and is not generally accepted in the scientific community. *See* FF ¶¶ 41, 42, 52-54.

24. Dr. Whysner testified that no reasonable scientist in the field of exposure assessment would recalculate laboratory results based upon three unconfirmed values from a split sample test obtained a year and a half earlier. FF ¶ 54. Moreover, Dr. Whysner testified as to the wealth of information available to Dr. Nisbet to properly evaluate the reliability of Plaintiffs' 1987 AML blood results. FF ¶¶ 49, 50, 52, 53. Dr. Whysner stated that it is standard procedure in the field of exposure assessment to contact a laboratory and review its procedures if you question the reliability of certain results. Dr. Nisbet failed to follow this practice. FF ¶ 41.

25. Dr. Nisbet has failed to identify any literature supporting his recalculation of the 1987 AML results nor has his methodology been endorsed by other experts in field of exposure assessment. Thus, there is no likelihood that Dr. Nisbet's methodology has been exposed to "critical scientific scrutiny." This factor weighs against admissibility. *See Downing*, 753 F.2d at 1238-39.

26. Dr. Nisbet based his opinion regarding the unreliability of the 1987 AML results on unsupported and false assumptions. First, Dr. Nisbet assumed that the 1986 AML results were two and a half to three times too low rather than that the Michigan State Laboratory results were two and a half to three times too high. Dr. Nisbet based this conclusion on his belief that the Michigan State Laboratory was "more reliable." FF ¶ 38. Dr. Whysner testified that it is common practice in the scientific community to contact the laboratory and request data regarding a sample testing if you think there is a problem with the split sample results. FF ¶ 41. Dr. Nisbet did not request this information. After seeing this information, Dr. Nisbet adopted an additional theory that both AML and Michigan State Laboratory could be unreliable. FF ¶ 42.

27. His next assumption was that AML's results would generally always be two and a half to three times too low.

FF ¶ 38. Dr. Nisbet failed to point to any evidence to support this assumption. Moreover, he concedes that he has no information that AML was in fact following the same procedures in August of 1987 as it did in March of 1986. FF ¶ 51.

28. Furthermore, Dr. Nisbet disregarded inter-laboratory comparison data and proficiency test results that were available after the 1986 split sample tests. This data would have enabled him to evaluate the 1987 AML results based upon data and results that were more substantial and information that was more recent regarding the conditions at AML and its comparison to Michigan State Laboratory in August of 1987. *See* FF ¶¶ 52, 53.

29. Dr. Nisbet also based his opinion that the 1987 AML results are unreliable on two erroneous factual assumptions. First, he stated that AML back-up data and quality control information was not available to evaluate the 1987 AML results. This information in fact was available and was admitted into evidence at the hearing. FF ¶¶ 49, 50. Second, Dr. Nisbet stated that the 1987 samples were stored for over a month and that the storage conditions may have affected the samples. These samples were in reality stored for approximately two weeks. FF ¶ 47. In addtion, Dr. Nisbet admitted that he had no information that the samples were stored improperly. FF ¶ 48.

30. I find that Dr. Nisbet's conclusion that Plaintiffs' 1987 AML results are unreliable is based upon unsupported factual assumptions and will not aid or assist the jury in reaching "accurate conclusions" under Rule 702. Furthermore, Dr. Nisbet's failure to review AML's quality control information, inter-laboratory comparison data and proficiency test results renders his testimony scientifically unreliable and legally inadmissible.

31. With regard to Dr. Nisbet's back-calculations, Plaintiffs and Defendants agree that the *Downing* test for novel scientific evidence is the appropriate standard to

review Dr. Nisbet's back-calculations of the 1992 Eco Logic results.

32. Dr. Nisbet estimated Plaintiffs' PCB blood levels as of 1986 based a recalculation of Plaintiffs' 1992 PCB blood levels recorded by Eco Logic. Dr. Nisbet assumes that Plaintiffs had high levels of PCB exposure prior to 1986. He attempted "to estimate the degree possible, although not very quantitatively, but I attempted to estimate the range of possible magnitudes of [Plaintiffs' PCB] exposure, based on the most reliable set of data, which was the blood measurements taken in 1992. FF ¶ 65.

33. Dr. Nisbet utilized the 1992 Eco Logic PCB blood levels to perform a back-calculation based upon various assumptions regarding the half-lives of the PCBs and likelihood of continuing exposure from other sources. FF ¶ 67. Dr. Nisbet projected Plaintiffs' possible "range" of PCB exposure as of 1986. FF ¶ 68.

34. Dr. Nisbet's back-calculation under these circumstances was not an application of a recognized methodology. FF ¶ 70. Dr. Whysner stated that "I have never seen [back-calculations] used in this kind of situation;" this is unprecedented and not valid. *Id.* Dr. Whysner went on to state that "the major [problem with Dr. Nisbet's methodology] is that . . . you have to assume the thing that you are trying to prove in the first place." *Id.*

35. I find that Dr. Nisbet's method of back-calculating Plaintiffs' 1992 PCB blood levels to 1986 presupposes exactly what he is trying to establish which is unusual prior exposure to PCBs by Plaintiffs.

36. Moreover, Dr. Nisbet's rough estimates of Plaintiffs' 1986 PCB blood levels through his back-calculations are completely speculative and likely to lead to erroneous results. These rough estimates of Plaintiffs' "potentials" for exposure will not aid or assist the jury under Rule 702.

37. Dr. Nisbet failed to cite any literature that supports his use of back-calculations when estimating unknown prior exposure to toxic chemicals in an environmental situation. *See* FF ¶¶ 80-82. Nor has this methodology been endorsed by other experts in field of exposure assessment. Thus, Dr. Nisbet's methodology has not been exposed to scientific scrutiny. Dr. Nisbet does not cite a single study that measures PCB blood levels directly without adjusting the laboratory results through his own calculations.

38. Dr. Nisbet failed to present any evidence that his recalculations of the 1987 AML data and his back-calculations of the 1992 Eco Logic data have been put to any "non-judicial use." *Downing,* 753 F.2d at 1239. This also weighs against the admissibility of his methodology.

39. I conclude that it is not scientifically valid for Dr. Nisbet to use back-calculations to prove Plaintiffs' prior exposure to PCBs under the circumstances of this case. Dr. Nisbet's back-calculations in this situation are unprecedented and unreliable, and must be excluded.

40. Dr. Nisbet's methodology regarding back-calculations was also found unreliable by the court in *Carroll v. Litton Systems, Inc.*, No. B-C-88-253, 1990 U.S. Dist. LEXIS 16833 (W.D.N.C. Oct. 29, 1990).[1] The court excluded the testimony of the plaintiffs' exposure expert who back-calculated the levels of plaintiffs' past exposure to trichloroethylene ("TCE") using estimated half-lives of the chemicals. The court in *Carroll* stated that the expert's "method of determining historical concentrations has no recognition, or even reference, in any scientific literature, in learned treatises, or in any actual application," and that half-lives are used prospectively only. *Id.* at *34.

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[1] *Carroll* was written by a United States Magistrate and was adopted by the district court by order dated July 15, 1991.

II. *EXCLUSION BASED UPON RULE 703*

41. Rule 703 of the Federal Rules of Evidence ("Rule 703") provides that:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

42. Rule 702 deals with examining the method by which the data is analyzed while Rule 703 deals with examining the underlying data that an expert analyzes. *Paoli,* 916 F.2d at 856.

43. The proper inquiry is not what the court considers reliable, but what experts in the relevant discipline consider to be reliable. *Japanese Electronic,* 723 F.2d at 276 (citations omitted).

44. This Court has a "proper and reviewable foundation for making its admissibility findings," *Paoli,* 916 F.2d at 853, and has conducted the requisite factual inquiry under *Japanese Electronic* to determine what type of facts or data experts in the field of exposure assessment find reliable. 723 F.2d at 276.

45. I find that Dr. Whysner is well qualified to testify as to what facts or data experts in the field of exposure assessment rely upon to reach their conclusions. FF ¶¶ 2-9.

46. Dr. Nisbet recalculated Plaintiffs' 1987 AML blood results by inflating these results by a factor of two and a half to three. He arrived at his "correction factor" by comparing values obtained from three split samples in 1986 from AML and Michigan State Laboratory. FF ¶¶ 38, 39.

47. In all the years Dr. Whysner has been doing exposure assessments, he stated that he had never seen an expert use results from three split samples to recalculate results obtained from the same lab a year and a half later. FF ¶ 54.

48. I conclude that the 1986 data obtained from the three split samples and the "recalibrated" 1987 AML results based upon Dr. Nisbet's correction factor are not data of the type reasonably relied upon by experts in the field of exposure assessment as required under Rule 703. Thus, Dr. Nisbet's testimony that is based upon this data must be excluded.

49. Dr. Nisbet also lowered the general population background PCB blood levels by using results obtained in NHATS. This was a study which analyzed fat samples not blood samples for the presence of PCBs in the general population. FF ¶ 57. Dr. Whysner testified that NHATS reported PCB fat levels in ranges because the data was not accurate enough or reliable enough to arrive at the average PCB levels in the fat tissue. FF ¶ 58.

50. Dr. Nisbet used the NHATS fat data to estimate the total amount of PCBs in the blood of the average person in the United States. He estimated a lower background PCB blood level by using a partitioning coefficient which was a ratio of the amount of PCBs in the blood and amount of PCBs in the fat. FF ¶ 59.

51. Experts in the field of exposure assessment do not reasonably rely upon NHATS fat data to calculate background PCB blood levels. *Id.*

52. I conclude that Dr. Nisbet's recalculation of the background PCB blood levels through use of the NHATS fat data is not data of the type reasonably relied upon by exposure assessment experts. Accordingly, any testimony of Dr. Nisbet that relies upon this data must be excluded.

53. Defendants argue that Eco Logic's 1992 results should also be excluded pursuant to Rule 703. The 1992 Eco Logic results form the sole basis for Dr. Nisbet's back-calculations. I have concluded in another memorandum which addresses Defendants' Motion *In Limine* to Exclude Results of Analyses Performed by Eco Logic to exclude the Eco Logic data under Rule 703 since it is not of the type reasonably relied upon by experts in the field of exposure assessment. Thus, Dr. Nisbet's testimony concerning the 1992 Eco Logic results must be excluded under Rule 703.

For the foregoing reasons, I find that Dr. Nisbet is not qualified to testify as an expert in this case under Rules 702 and 703 of the Federal Rules of Evidence. Therefore, I shall enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *SEPTA, et al.*	No. 86-2235
John Ingram, et al. v. *SEPTA, et al.*	No. 86-7561
Andre Williams v. *SEPTA, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *SEPTA, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Ian C.T. Nisbet, Ph.D., all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX III-C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Cathlene Brown, et al. v. *SEPTA, et al.*	No. 86-7415
Celeste Brown, et al. v. *SEPTA, et al.*	No. 86-7416
Christopher S. Brown, et al. v. *SEPTA, et al.*	No. 86-7414
Clemmon Brown, et al. v. *SEPTA, et al.*	No. 86-7420
Cloyd Brown, et al. v. *SEPTA, et al.*	No. 86-7421
Craig Brown, et al. v. *SEPTA, et al.*	No. 86-7419
Curtis Brown, et al. v. *SEPTA, et al.*	No. 86-7422
Mary Retta Johnson, v. *SEPTA, et al.*	No. 86-7418
Margherita Barbetta, v. *SEPTA, et al.*	No. 86-7417

MEMORANDUM

R.F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE THE
TESTIMONY OF
G. JOHN DiGREGORIO, M.D., Ph.D.

Before the Court is Defendants' Motion to Exclude the Testimony of G. John DiGregorio, M.D., Ph.D. ("Dr. DiGregorio").[1] Dr. DiGregorio is to testify in this toxic

[1] Defendants in this matter are Monsanto Corporation, General Electric Company, Amtrak, Conrail, Southeastern Pennsylvania Transit Authority (SEPTA) and the City of Philadelphia.

tort case on behalf of nine individuals who claim to have been exposed to polychlorinated biphenyls ("PCBs") from the Paoli Railyard ("Railyard"), which is adjacent to their homes in Paoli, Pennsylvania.[2] Dr. DiGregorio is presented as an expert witness to testify that: 1) the Plaintiffs' present injuries were caused by PCB exposure; 2) the Plaintiffs are at an increased risk of developing future injuries due to their exposure to PCBs;[3] 3) the Plaintiffs have an increased fear of future injury and this fear is reasonable; and 4) a medical monitoring program, which he would design, should be implemented for the Plaintiffs.

Defendants seek to exclude this testimony on the grounds that it is based upon unreliable methodology and incomplete data. Furthermore, Defendants contend that his opinions concern subject matters which are outside of his field of expertise, and that his medical monitoring opinion was disclosed in an untimely fashion.

I. PROCEDURAL HISTORY

This case is before the Court on remand. In 1986, Plaintiffs filed their complaints alleging that they suffered various injuries from exposure to PCBs. This Court granted Defendants' Joint Motion for Summary Judgment in 1988. On appeal, the Third Circuit reversed that ruling and remanded this matter for further hearings.

The trial in this matter was scheduled to begin on August 3, 1992. Based on the numerous motions *in limine* filed by the parties, the Court heard six days of

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[2] Those plaintiffs are Cathlene Brown, Celeste Brown, Curtis Brown, Christopher Brown, Cloyd Brown, Craig Brown, Mary Retta Johnson and Margherita Barbetta. For the sake of clarification, Plaintiffs are grouped according to their counsel. The nine Plaintiffs in this action are collectively know as the "Hanes Plaintiffs", named after their counsel, Bruce Hanes.

[3] During oral argument, Plaintiffs' counsel withdrew the claim for increased risk of future injury due to PCB exposure. July 28, 1992 Hearing at 166-68.

testimony and argument concerning these motions. The Court shall now render its findings concerning the testimony of Dr. DiGregorio.

II. FINDINGS OF FACT

1. On June 4, 1991, this Court issued a Scheduling Order by which this case was to proceed. (Attached as Exhibit 1 to the Appendix to Defendants' Motion *in limine*.) This Order required Plaintiffs to supply Defendants with a list of all trial expert witnesses and the substance of their respective testimony by March 17, 1992. Defendants were to provide the same information to Plaintiffs by April 17, 1992. This Order established June 17, 1992 as the deadline for the deposition of all expert witnesses, and August 3, 1992 as the trial date.

2. Prior to the trial date, the parties filed numerous motions *in limine*. This Court heard six days of arguments and live testimony in support of both parties respective motions *in limine*.[4] The record for this particular motion consists of the testimony of Jordan N. Fink, M.D. ("Dr. Fink") July 28, 1992 Hearing Testimony of Dr. Fink ("Fink T.") and Paul M. Roediger, M.D. ("Dr. Roediger") July 28, 1992 Hearing Testimony of Dr. Roediger ("Roediger T."); the videotape deposition of Michael Weitekamp, M.D. ("Dr. Weitekamp") July 28, 1992 Hearing Testimony of Dr. Weitekamp ("Weitekamp Dep."); the transcripts of Dr. DiGregorio's five depositions (Attached as Exhibits 6-10 to the Appendix to Defendants' Motion *in limine*); Dr. DiGregorio's Curriculum Vitae (Attached as Exhibit 4 to the Appendix to Defendants' Motion *in limine*) ("DiGregorio CV"); his reports dated June 13, 1986 and April 21, 1986 (Attached to Exhibit 2 to the Appendix to Defendants' Motion *in limine*); and his Medical Surveillance Program dated

[4] The *in limine* hearings were held on July 28, 29, 30, 31 and August 3, 1992. On August 7, 1992, the Court heard oral arguments on the various motions *in limine* as well as the motion for summary judgment.

April 18, 1992 (Attached as Exhibit 3 to the Appendix to Defendants' Motion *in limine*) ("Surveillance Program").

3. Dr. DiGregorio received his bachelors degree from Pennsylvania State University in 1962. He received his Ph.D. in pharmacology from Hahnemann Medical College ("Hahnemann") in 1966, and his M.D. from Hahnemann in 1978. From 1978 to 1979 he served an internship in internal medicine at Hahnemann Hospital. Dr. DiGregorio completed his residency at Hahnemann in 1981, and became board eligible in internal medicine in that same year. He is licensed to practice in the Commonwealth of Pennsylvania and has been a professor of pharmacology and medicine at Hahnemann from 1981 to the present. During his career he has written in excess of thirty research articles and authored over twenty books. DiGregorio CV.

4. Dr. DiGregorio was deposed in this matter on April 4, April 26, June 2 and June 3, 1988. (Attached as Exhibits 6-9 to the Appendix to Defendants' Motion *in limine*) ("DiGregorio 1988 Dep.") The only other occasion in which he was deposed for this case was April 16, 1992. (Attached as Exhibit 10 to the Appendix to Defendants' Motion *in limine*) ("DiGregorio 1992 Dep.")

5. Dr. DiGregorio is presented as an expert witness on behalf of the Hanes Plaintiffs. He offers the opinions that the Plaintiffs' present injuries were caused by PCB exposure, that Plaintiffs have an increased fear of future injuries and such fear is reasonable, and that a medical monitoring program should be implemented for the Plaintiffs.

6. Dr. DiGregorio met with each plaintiff on one occasion in 1986.[5] He intended these initial visits to be

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[5] Dr. DiGregorio did meet again with Christopher Brown in March of 1988 to treat him for a rash. DiGregorio 1988 Dep. 430. He also saw Mary Retta Johnson on one other occasion in order to perform more blood work. *Id.* at 423.

merely "fact finding" meetings so he could obtain their histories and "get my facts in order". DiGregorio 1988 Dep. 204.

7. Dr. DiGregorio's evaluation of each plaintiff consisted of the following:

a) Each Plaintiff filled out a Medical Surveillance Check List ("check list"). This check list required Plaintiffs to mark the symptoms they had and answer various questions concerning their family medical history.

b) Upon completing the check list, each Plaintiff was interviewed by Dr. DiGregorio in order to discuss the responses on the check list.

c) Each Plaintiff had blood drawn in Dr. DiGregorio's office. This blood was tested and measured for PCB content.

d) Each Plaintiff had a fat biopsy performed at a local hospital. These biopsies were tested and measured for PCB content.[6] *Id.* at 193-94, 390.

8. Dr. DiGregorio did not perform a physical examination, did not perform a psychological examination, nor did he review medical records for any of the Plaintiffs. *Id.* at 341, 349, 397, 398, 429, 454-55, 475.

9. Based on this procedure, Dr. DiGregorio opined that the Plaintiffs had the following symptoms:

a) Craig Brown had a limited range of motion in his arms, legs, head and neck. He complained of headaches, a tumor on his breast, a heart murmur and arthritic pain. His blood test revealed that his LDH was elevated. *Id.* at 263-65, 268-69.

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[6] Cloyd Brown was not evaulated by Dr. DiGregorio for PCB exposure except to have a fat biopsy performed. Mr. Brown did not fill out a check list, was not interviewed by Dr. DiGregorio nor did he have any blood drawn. He was seen by Dr. DiGregorio in September of 1986 for a cyst on his thigh. DiGregorio 1988 Dep. 472-75.

b) Christopher Brown had hypertension and a heart murmur. His blood test revealed that he had a liver dysfunction and elevated triglyceride. *Id.* at 108-11, 439-40, 442-44.

c) Curtis Brown was irritable, had insomnia and a heart murmur. His blood test revealed that he had an abnormal liver function and elevated trigylceride. *Id.* at 347, 355, 359, 366.

d) Cathlene Brown bruised easily, had stiff joints, tender joints and swelling of the hands and feet. *Id.* at 374-75.

e) Mary Retta Johnson was irritable and suffered from insomnia, anxiety, depression and a sluggish thyroid. Her blood test revealed that she suffered from anemia. *Id.* at 396, 398, 417.

f) Celeste Brown had a thyroid problem and a heart murmur. *Id.* at 459-60, 464.

g) Margherita Barbetta checked that she developed diabetes in 1984. *Id.* at 458.

h) Clemmon Brown suffered from dizziness and high blood pressure. *Id.* at 467-68.

10. In addition to the above delineated symptoms, Dr. DiGregorio opined that each Plaintiff suffered from anxiety and an increased fear of developing future illnesses, most notably cancer. *Id.* at 323, 357, 384, 425.

11. In 1988, Dr. DiGregorio's diagnosis was that all of the Plaintiffs' symptoms were caused by exposure to PCBs "until proven otherwise." *Id.* at 377-78. Inconsistent with this diagnosis, Dr. DiGregorio admits that until he physically examines the Plaintiffs he is unable to know if they presently suffer from *any* injuries. *Id.* at 340, 41, 369-70, 384, 390, 400-01, 449-50, 465, 469. Furthermore, Dr. DiGregorio is unable to state an opinion as to whether any of the Plaintiffs will develop future injuries

due to PCB exposure. *Id.* at 343, 372, 390. The only opinion that Dr. DiGregorio is consistent in holding throughout his deposition is that the Plaintiffs' anxiety, fear of cancer, depression and abnormal lab values were caused by exposure to PCBs. *Id.* at 475-76.

12. In rendering his opinion that PCBs were the cause of all of the Plaintiffs' symptoms, Dr. DiGregorio failed to consider and further test for alternative causes of these symptoms. Most notably:

a) Dr. DiGregorio concluded that Craig Brown's elevated LDH, which is a liver enzyme, was caused by PCB exposure. In addition, he testified that alcohol is also a cause of elevated LDH. Dr. DiGregorio was unaware that Craig Brown admitted to his psychologist that he drank a few cans of beer every work night, and 2 to 3 six packs on Thursday, Friday and Saturday nights. *Id.* at 313-15. However, Dr. DiGregorio testified that this knowledge of Craig's drinking habits would not affect his opinion that PCB exposure was the cause of Craig Brown's elevated LDH. *Id.* at 313-15.

b) Cathlene Brown checked that she bruised easily. *Id.* at 374. Without performing a physical examination to verify that she did in fact have bruises, Dr. DiGregorio concluded that her bruising was caused by PCB exposure. *Id.* at 375-76. Even though Cathlene Brown was taking the birth control pill Ortho-Novum and that a side effect of this is bruising, Dr. DiGregorio maintained that PCB exposure was the cause of her bruising. *Id.* He stated that he would continue to hold this opinion until he had the opportunity to further investigate the matter "either by physical examination or more tests. . . ." *Id.* at 377.

c) Curtis Brown checked that he was irritable and had insomnia. *Id.* at 347. Dr. DiGregorio stated that there are many causes of insomnia and irritability and that they are non-specific symptoms. *Id.* at 350. How-

ever, without reviewing Curtis Brown's medical records or performing a physical examination of him, Dr. DiGregorio concluded "to a reasonable degree of medical certainty" that PCB exposure was the cause of his insomnia and irritability. *Id.* at 349-51. Dr. DiGregorio conceded that this was merely his preliminary opinion and that this opinion may change upon future physical examinations and tests. *Id.* at 349-50.

d) Dr. DiGregorio testified that Curtis Brown's elevated triglycerides, as revealed by his blood tests, was caused by PCB exposure. *Id.* at 366. When questioned about the type of blood sample he used, Dr. DiGregorio stated that he used a non-fasting blood sample. He admitted that the use of a non-fasting blood sample tended to incorrectly show elevated triglycerides. *Id.* at 364-65. In fact, he stated that to get a "true value of triglycerides", one should use a fasting blood sample rather than a non-fasting sample. *Id.* at 364-66. He also stated that obtaining a fasting blood sample would be the first thing that he would do to determine the cause of Curtis Brown's elevated triglycerides. *Id.* at 366. In addition, Dr. DiGregorio stated that diet and hypertension can cause elevated triglycerides, but he did not inquire into Curtis Brown's diet or stress level. *Id.* at 366-68. Even though Dr. DiGregorio used a less reliable non-fasting blood sample and did not consider Curtis Brown's diet or stress level, Dr. DiGregorio opined "with a reasonable degree of medical certainty, his elevated triglycerides are due do [sic] to PCB [exposure]." *Id.* at 365-67.

13. During his deposition in 1988, Dr. DiGregorio described his methodology which led him to diagnose PCB exposure as the cause of all of the Plaintiffs' symptoms.

> A. When a doctor does a history and there's a cause of a problem, whether it's pneumonia, pulmonary tract infection, and the differential diagnosis—the leading differential diagnosis at

the time is what the doctor suspects is the immediate cause of the problem.

And it's up to the doctor to proceed after that point and to prove either by physical examination or more tests whether his diagnosis is correct.

So, as far as I'm are [sic] concerned the symptoms that these patients gave me in the history are due to PCB exposure. Until I have the opportunity to continue on with my investigation they all will have, within a reasonable degree of medical certainty, that type of symptom.

Q. I don't mean to put words in your mouth, but isn't that really the preliminarily [sic] assessment or preliminary diagnosis?

A. That's what I've been telling you all along now. I only preliminarily saw these individuals. It's a diagnosis at this time.

Id. at 377-78.

14. Dr. DiGregorio concedes that, based on the limited information he had, he is unable to make a final diagnosis. In addition, he must prove his preliminary diagnosis before he can render a final opinion. *Id.* at 379.

15. As Dr. DiGregorio attested to, since he did not perform a physical examination of these Plaintiffs, he cannot verify the *existence* of their claimed injuries. *Id.* at 268-69, 356, 398, 449-50, 475. Furthermore, Dr. DiGregorio did not inquire into whether the Plaintiffs had seen a doctor for these claimed injuries. I find that Dr. DiGregorio merely assumed that the Plaintiffs suffered from these problems, and he failed to verify this through any medical examination or procedure.

16. Dr. DiGregorio testified that "[t]he plan was to continue on as a follow-up [basis] and to do physical

examinations . . . ." *Id.* at 354. These follow-up visits were necessary in order to prove whether or not his initial diagnosis was correct. *Id.* at 377. These follow-up visits would consist of obtaining a complete medical history of each Plaintiff, performing physical examinations and more blood tests as the physical examinations showed necessary, performing a chronological exposure history, and studying the type of exposure that the Plaintiffs were subject to as well as its source. *Id.* at 304-05, 354, 385-86, 510-12. When asked in 1988 how long it would take to complete these follow-up visits, Dr. DiGregorio believed that everything could be concluded within six months. *Id.* at 510-12.

17. Dr. DiGregorio also testified that all of the Plaintiffs had an increased fear of developing future illnesses, most notably cancer. *Id.* at 99-100. He stated that he "can determine as a physician whether the person is under a great deal of stress, or a lot of anxiety, or a lot of fear." *Id.* at 208. However, Dr. DiGregorio admitted that he could not quantitate that increased fear because he is not an expert at measuring fear. *Id.* at 207. Dr. DiGregorio admitted that his determination that the Plaintiffs had a high degree of anxiety and an increased fear of developing cancer was purely subjective. *Id.* at 341. Furthermore, he did not perform a psychological examination of any of the Plaintiffs. *Id.* at 321, 349, 398, 429, 439, 454-55. According to Dr. DiGregorio, there are tests that can be performed to quantitate fear, but he is not able to perform those tests, and to his knowledge, none of these tests have been performed on the Plaintiffs. *Id.* at 211-12.

18. Dr. DiGregorio further opined that the Paoli Railyard was the source of the PCBs to which the Plaintiffs were exposed. *Id.* at 303-04. He did not have any data as to the levels of PCBs in the Railyard or in the Plaintiffs' living areas when he made this statement. *Id.* He was told by various Plaintiffs that they had been ex-

posed to PCBs, to PCB dust and vapors, and that they could smell the PCBs. *Id.* at 254-55, 267-68, 352, 430-31. Dr. DiGregorio merely relied on these statements in concluding that the PCBs came from the Paoli Railyard.

19. In the four years since stating that follow-up visits were necessary in order for him to make a final diagnosis, Dr. DiGregorio has yet to see any of the Plaintiffs for these follow-up visits, nor has he "done anything with them." DiGregorio 1992 Dep. 55. In addition, he testified that he has not performed any more research "with respect to the relationship between [the] level of exposure of PCBs, and [the] cause of illness or any kind of illness." *Id.* Dr. DiGregorio has not performed physical examinations of the Plaintiffs, has not reviewed their medical records and has not had any additional lab work done. *Id.* at 14, 32-33, 55.

20. In his 1992 deposition, Dr. DiGregorio stated that the Plaintiffs should be the subjects of a medical monitoring program. *Id.* at 28. According to Dr. DiGregorio, this is necessary because Plaintiffs are at an increased risk of contracting various illnesses due to their exposure to PCBs. *Id.* at 25-26, 35-36. Since PCBs affect several organs in the body, this comprehensive monitoring program would provide a method for the early detection of any illness. *Id.* at 36, 65-66. As of his 1992 deposition, Dr. DiGregorio had not been requested to develop a monitoring program for the Plaintiffs. *Id.* at 29. In fact, when questioned by Defendants' counsel on this matter, Dr. DiGregorio refused to answer any questions regarding a medical monitoring program because one had yet to be developed. However, on April 18, 1992, *two days* after this deposition, Dr. DiGregorio submitted to Plaintiffs' counsel his Medical Surveillance Program in which he outlined the monitoring that the Plaintiffs should undergo for at least the next twenty-five years.

21. As was the case in 1988, Dr. DiGregorio cannot quantify Plaintiffs' increased risk of getting cancer or any other illness due to PCB exposure. *Id.* at 57-58. In fact,

Dr. DiGregorio merely assumes that all of the Plaintiffs are extremely sensitive to PCBs, such that even the slightest exposure will cause serious injuries. *Id.* at 76.

22. At the *in limine* hearing, Defendants presented the live testimony of Dr. Fink, Dr. Roediger and the video tape deposition of Dr. Weitekamp. These witnesses outlined the proper methodology that physicians must follow in rendering a medical diagnosis. These expert witnesses were presented specifically to rebut the testimony of Janet D. Sherman, M.D. ("Dr. Sherman"), but I find their testimony equally applicable to the methodology of Dr. DiGregorio.

23. Defendants offered Dr. Fink as an expert in internal medicine and immunology. Dr. Fink graduated with a bachelors degree from the University of Wisconsin in 1956. He obtained his M.D. from the University of Wisconsin Medical School in 1959. After two years of rotating internships, Dr. Fink performed a three year residency in internal medicine at Milwaukee County General Hospital. During his career, Dr. Fink has written in excess of 230 articles and has performed research concerning unusual lung diseases and the immune responses of the lungs. Dr. Fink is currently a Professor of Medicine as well as Chief of the Allergy and Immunology Division at the Medical College of Wisconsin. He teaches immunology and serves on various committees which oversee the quality of the clinical care rendered by the physicians at the Medical College. He is board certified in allergy and immunology as well as internal medicine. His current practice consists of seeing sixteen new patients and one hundred return patients per week. In addition, he makes internal medicine ward rounds six weeks out of the year. Fink T. 11-16.

24. At the *in limine* hearings, Dr. Roediger was offered as an expert in internal medicine. Dr. Roediger graduated with a bachelors degree from Princeton University in 1954. After obtaining his M.D. from Thomas

Jefferson University Hospital in Philadelphia in 1958, Dr. Roediger served a one year internship and a three year residency in internal medicine at Abington Memorial Hospital. Since 1963, Dr. Roediger has been the Director of Medical Education for the hospital, which currently has eighty residents in training. In this capacity, Dr. Roediger has managed the internal medicine program and been the administrator for all four primary care programs as well as staff qualifications and licensure. In 1972, he was appointed Physician and Chief of General Internal Medicine, a position which he holds to this day. Dr. Roediger is also responsible for the quality of care offered by the internists at the hospital. He is board certified and his current practice consists of seeing approximately 125 patients per week. Roediger T. 93-97.

25. By means of videotape deposition, Defendants offered Dr. Weitekamp as an expert in internal medicine and immunology. Dr. Weitekamp received his M.D. from Georgetown University in 1977. He then went to Hershey Medical Center where he was trained in internal medicine and infectious diseases. From 1985 to 1990, Dr. Weitekamp was Chairman of the Department of Medicine at Polyclinic Medical in Harrisburg. At Polyclinic, Dr. Weitekamp served on the Medical Resident Clinical Competency Committee, Medical Education Committee and the Quality Assurance Committee. Dr. Weitekamp is currently Chief of the Division of Internal Medicine at Hershey. He is also an associate professor in internal medicine and infectious diseases at Penn State University, where he teaches medical students and residents. Dr. Weitekamp has published eleven peer review articles and authored chapters in four text books. He is licensed to practice in Pennsylvania, and he currently has an office practice in internal medicine and infectious diseases. In addition, he serves as an attending physician in a teaching setting for four months out of the year. Weitekamp Dep. 6-10.

26. During the *in limine* hearings, Drs. Fink, Roediger and Weitekamp testified as to the proper process that a physician should follow when diagnosing a patient's illness. That process is as follows:

a) It begins by asking the patient what is his/her chief complaint.

b) Then a history is taken which "delves into the chief complaint and expands the nature, the timing, the associated complaints that the patient might have." Fink T. 18-19.

c) Then the symptoms are reviewed to determine which organs are involved in the illness.

d) A past medical history is taken.

e) A social history is taken, which would pertain to the patient's drug, smoking, drinking and sexual habits.

f) A physical examination would then be performed with an emphasis placed on the chief complaint.

g) After all of the above is completed, a differential diagnosis is performed in order to determine the cause of the patient's complaint. A differential diagnosis consists of listing the possible diagnoses, examining each and "ruling in" those that appear to be the likely cause and "ruling out" those that do not appear to be the cause. Additional tests may be run which will support or eliminate some of the diagnoses.

h) If several diagnoses remain, then a more extensive evaluation of the patient is required. This necessitates running more tests, asking more questions and examining medical records until the problem is resolved. Fink T. 17-19, Roediger T. 117-22, Weitekamp Dep. 60-62.

27. These expert witnesses testified that performing a differential diagnosis is the fundamental duty or the "hallmark" of internal medicine. Fink T. 43, Roediger T. 117, Weitekamp Dep. 62. Without considering alternative causes, and then ruling them in or out as a cause of the

patient's complaint, a physician's diagnosis is "totally unreliable." Fink T. 43.

28. This Court finds that reliable medical methodology requires a physician to perform a differential diagnosis and thus, evaluate alternative causes before rendering an opinion as to the cause of an illness.

29. In fact, this is precisely what Dr. DiGregorio intended to do in his follow-up visits with the Plaintiffs. He intended to perform physical examinations, take medical histories, perform more tests and study the source and amount of Plaintiffs' exposure. DiGregorio 1988 Dep. 304-05, 354, 385-86, 510-12. This needed to be performed so that he may render a correct, final diagnosis. However, Dr. DiGregorio testified that this has not been done in the six years since he has first seen the Plaintiffs. DiGregorio 1992 Dep. 55.

III. CONCLUSIONS OF LAW

1. This Court held *in limine* hearings as advised by *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985) to examine the admissibility of the testimony of the Hanes Plaintiffs' expert witness, G. John DiGregorio, M.D., Ph.D. Findings of Fact ("FF") ¶ 2. In addition to the motions and exhibits filed, the Court heard live testimony and oral arguments concerning the admissibility of Dr. DiGregorio's testimony. FF ¶ 2.

A. *Present Injuries and Causation*

2. Defendants seek to exclude Dr. DiGregorio's testimony regarding the injuries that the Plaintiffs currently have and their respective causes. Defendants claim that his opinions are based on unaccepted methodology and inadequate data, and are therefore inadmissible under Federal Rules of Evidence 702 and 703. ("Rule 702") ("Rule 703").

1. *Rule 702*

3. Defendants contend that Dr. DiGregorio's methodology is unreliable, and as such should be excluded pursuant to Rule 702.[7] "When it is a scientist's methodology that is being attacked, in contrast to the data relied on, the court must analyze the reliability of that methodology under . . . Rule 702." *In re Paoli R.R. Yard PCB Litigation,* 916 F.2d 829, 856-57 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight,* 111 S. Ct. 1524 (1991). Defendants attack Dr. DiGregorio's methodology which consisted of seeking each Plaintiff on one occasion, having each Plaintiff fill out a check list of symptoms, interviewing each Plaintiff concerning this check list, and performing a blood test and a fat biopsy. FF ¶ 7.

4. Plaintiffs argue that the Defendants' failure to put forth any testimony which directly contradicted Dr. DiGregorio's methodology compels the admission of him as an expert witness. Plaintiffs are incorrect in their asessment. Drs. Fink, Roediger and Weitekamp all testified as to the proper methodology that should be followed in diagnosing an illness. FF ¶¶ 2, 22-28. Even though their testimony was used to directly contradict the testimony of Dr. Sherman, it has been found to be equally applicable to Dr. DiGregorio. FF ¶¶ 22, 28. Furthermore, Defendants are not required to produce testimony which directly contradicts the opinions of Dr. DiGregorio. The only requirement is that "there be a developed record and specific findings on reliability issues." *Paoli,* 916 F.2d at 858. This Court has complied with that requirement. FF ¶ 2.

5. The testimony of Defendants' experts demonstrates that the methodology used by Dr. DiGregorio is neither

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[7] Rule 702 states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

standard nor reliable. FF ¶¶ 22-28. Defendants' expert witnesses testified that a physician must perform a physical examination, medical and social histories as well as differential diagnosis before rendering a final opinion. FF ¶¶ 26-28.

6. Furthermore, and of greater significance, Dr. DiGregorio did not follow the methodology that *he* proposed would be necessary to render a proper final diagnosis. FF ¶¶ 14, 16, 29. The methodology that he intended to follow would consist of a complete medical history of each Plaintiff, a physical examination, performing more blood tests as well as other tests that the physical examination showed necessary, performing a chronological exposure history and studying the type of exposure that the Plaintiffs were subject to as well as its source. FF ¶ 16. It is undisputed that Dr. DiGregorio did not follow this methodology. FF ¶¶ 29. As a result, Dr. DiGregorio is only able to render a preliminary diagnosis. FF ¶¶ 13-15, 29.

7. Rule 702 calls for the admission of an expert's testimony "so long as it is rendered by a qualified expert and is helpful to the trier of fact". *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). This helpfulness requirement is the "touchstone of Rule 702." *United States v. Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985). The Court is cautioned that, "in making reliability determinations, courts must err on the side of admission rather than exclusion." *Paoli*, 916 F.2d at 857. However, "expert testimony that is based on unreliable methodology is unhelpful and therefore excludable." *DeLuca*, 911 F.2d at 954.

8. In his 1988 deposition, Dr. DiGregorio stated that he intended to perform various tests in his follow-up visits with each Plaintiff in order to prove or disprove his preliminary diagnosis. FF ¶ 16. However, as of four years later, Dr. DiGregorio has yet to see any Plaintiff on a follow-up visit nor has he "done anything with

them." FF ¶¶ 19, 29. He has not proved or disproved his preliminary diagnosis to the Plaintiffs, the Court, or more importantly, himself.

9. Dr. DiGregorio's intentions were proper methodology, but his actions, or lack thereof, were not. It is this incompleteness which "so altered [the methodology] as to skew the methodology itself" and renders it unreliable. *Paoli*, 916 F.2d at 858. Without the *performance* of proper methodology, Dr. DiGregorio's opinions are only preliminary, and as such are unhelpful to the jury. Since this incomplete methodology is unhelpful to the jury, his opinion on this matter is excluded pursuant to Rule 702.

10. In further support of their Rule 702 argument, Defendants contend that Dr. DiGregorio's testimony should be excluded because he failed to consider alternative causes of Plaintiffs' alleged injuries as required by proper methodology. FF ¶¶ 12, 26-28. Drs. Fink, Roediger and Weitekamp testified that proper methodology demands that the physician perform a differential diagnosis, which is ruling in or ruling out alternative causes of the patient's injury. FF ¶¶ 26-28. Plaintiffs correctly maintain that Dr. DiGregorio need not rule out all other possible causes of the symptoms in order to be admitted as an expert. However, he is not asked to rule out all other possible causes of Plaintiffs' injuries. He is merely expected to use proper methodology in rendering an opinion concerning a patient's injuries. This proper methodology requires that he evaluate alternative causes so that he may render the correct diagnosis. FF ¶¶ 26-28. After all, the purpose of an expert witness is to assist the trier of fact in rendering an intelligent, sound and correct verdict. *Viterbo v. Dow Chemical*, 826 F.2d 420, 422 (5th Cir. 1987). This is achieved by the expert isolating the cause of the injuries and providing supporting medical reasons for the diagnosis. Dr. DiGregorio's failure to evaluate alternative causes of Plaintiffs' alleged injuries forces the jury to arbitrarily choose one cause from a plethora of possible causes, and no medical foundation to aid them in

making that choice. FF ¶ 12. Therefore, I conclude that Dr. DiGregorio's unsupported opinion does not give the finder of fact a better understanding of the cause of Plaintiffs' alleged injuries.

11. Plaintiffs are also correct in their statement that to meet the standard for admissibility in this Circuit, it need only be shown that PCBs were a substantial contributing factor in Plaintiffs' injuries, not the only factor. *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 492 (3d Cir. 1985). However, Dr. DiGregorio admits that until he performs a physical examination, he is unable to verify the *existence* of the Plaintiffs' claimed injuries. FF ¶¶ 11, 13-15. For instance, Craig Brown and Christopher Brown each stated they had heart murmurs, but in both cases Dr. DiGregorio did not listen to their hearts, which he testified was necessary to do in order to determine the existence of a heart murmur. FF ¶¶ 9, 11, 15. Craig Brown stated that he had a tumor on his breast, but Dr. DiGregorio did not examine Craig for this alleged tumor. FF ¶¶ 9, 11, 15. Clemmon Brown stated that he had high blood pressure, yet Dr. DiGregorio did not take Clemmon's blood pressure, nor did he inquire into whether Clemmon was on any medication for that problem. FF ¶¶ 9, 11, 15. This Court is unable to fathom how it is possible for Dr. DiGregorio to testify that PCBs were a "substantial contributing factor" to Plaintiffs' injuries when he does not know if the Plaintiffs have any injuries. *Van Buskirk*, 760 F.2d at 492.

12. Because Dr. DiGregorio failed to have follow up visits with the Plaintiffs, failed to consider alternative causes of Plaintiffs' alleged injuries and failed to verify the existence of Plaintiffs' complaints, this Court concludes that his methodology is incomplete and therefore unreliable. As such, the testimony of Dr. DiGregorio is unhelpful to the finder of fact and excluded pursuant to Rule 702.

2. *Rule 703*

13. Defendants also assert that Dr. DiGregorio's testimony should be excluded pursuant to Rule 703 because it relies on data that experts in the field do not find reliable.[8] Rule 703 is used to determine if "an expert's testimony is based on the type of data a reasonable expert in the field would use in rendering an opinion on the subject at issue. . . ." *Paoli*, 916 F.2d at 857. In analyzing a Rule 703 motion, this Court adheres to the principle that "the proper inquiry is not what the court deems reliable, but what experts in the field find reliable." *In re Japanese Elec. Prod.*, 723 F.2d 238, 277 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). The Court has held *in limine* hearings to "make a factual inquiry and finding as to what data experts in the field find reliable." *Id.*; FF ¶ 2.

14. Due to his incomplete and therefore unreliable methodology, the data that Dr. DiGregorio relies upon is likewise unreliable. In forming his opinion that the cause of Plaintiffs' symptoms resulted from exposure to PCBs, Dr. DiGregorio considered the check list that Plaintiffs filled out, a brief interview he held with each Plaintiff and the results from the fat and blood tests. FF ¶¶ 7, 13, 14. As shown by Defendants' expert witnesses, this data alone is inadequate and unreliable to form a medical opinion. FF ¶¶ 26-28. There exists an abundance of other information that reasonable medical personnel should explore before rendering a diagnosis, including performing a complete physical examination; performing medical and social histories; reviewing medical

[8] Rule 703 states:

> The facts of data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

records; and performing a differential diagnosis. FF ¶¶ 26-28. Dr. DiGregorio did not have any of the important information that is ascertained from these medical procedures when he rendered his diagnosis. FF ¶¶ 13, 14, 16. Furthermore, Dr. DiGregorio admits that he needs to explore this other information before rendering a final opinion to "a reasonable degree of medical certainty." FF ¶¶ 11, 13-14.

15. Because experts in the field do not rely upon incomplete information in rendering a diagnosis, Dr. DiGregorio's testimony pertaining to causation is excluded pursuant to Rule 703.

B. *Fear of Future Illnesses*

16. Dr. DiGregorio is also offered as an expert to testify that Plaintiffs have an increased fear of developing future illnesses, that this increased fear stems from their exposure to PCBs and that this fear is reasonable. Defendants challenge his opinion on the grounds that Dr. DiGregorio is not qualified to render this opinion and that his methodology is unreliable. As such, Defendants contend that his opinion should be excluded pursuant to Rule 702.

17. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert and is helpful to the trier of fact." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). In interpreting Rule 702, this Court recognizes the established "liberal policy of permitting expert testimony which will 'probably aid' the trier of fact." *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110, 114 (3d Cir. 1987) (quoting *Knight v. Otis Elevator Co.*, 596 F.2d 84, 87 (3d Cir. 1979)). However, when that witness seeks to testify to facts and conclusions about which he does not possess expertise, that testimony is deemed not admissible. *Wilkinson v. Rosenthal & Co.*, 712 F. Supp. 474, 478 (E.D. Pa. 1989). At the very

minimum, an expert "must possess skill or knowledge greater than the average layman" concerning the area about which the witness seeks to testify. *Aloe Coal,* 816 F.2d at 114.

18. By his own admission, Dr. DiGregorio is not qualified to measure fear in an individual. FF ¶ 17. He is unable to quantify that fear in any manner other than to say that it is increased. FF ¶¶ 17, 21. He is not a psychiatrist nor is he a psychologist. Dr. DiGregorio is a pharmacologist and as such his professional expertise is not in the area of mental health. FF ¶ 3.

19. Recognizing that the "insistence on a certain kind of degree or background is inconsistent with our jurisprudence in this area", the Court is unaware of anything outside of his profession that would qualify Dr. DiGregorio as an expert in this area. *Paoli,* 916 F.2d at 855. While he states that he is able to recognize fear in individuals, no evidence is proffered to show that this ability is any "greater than [that of] the average layman." *Aloe,* 816 F.2d at 114; FF ¶ 17. Dr. DiGregorio does not possess any specialized skill or knowledge that would assist the jury in determining Plaintiffs increased fear, as required under Rule 702.

20. Therefore, I agree with the court in *Friedman v. F.E. Myers Co.,* 706 F. Supp. 376, 381 (E.D. Pa. 1989), in concluding that Dr. DiGregorio is not qualified to testify as an expert concerning Plaintiffs' claims of increased fear. As a result, his opinion on this matter is excluded pursuant to Rule 702.

21. In further support of their argument to exclude Dr. DiGregorio's testimony, Defendants contend that his methodology is unreliable. In rendering his opinion that Plaintiffs suffer from an increased fear of developing future illnesses, Dr. DiGregorio did not perform any mental examinations, take any mental health histories or administer any tests to measure the Plaintiffs' alleged fear. FF ¶¶ 8, 17, 29. In formulating this opinion, Dr. Di-

Gregorio merely relies on Plaintiffs' statements that they were concerned about getting future illnesses as a result of their exposure to PCBs. FF ¶¶ 10-11, 17-18. There is no *medical* basis for his opinion. Dr. DiGregorio admits this when he testifies that his opinion on this matter is purely subjective. FF ¶ 17. This opinion is merely Plaintiffs' statements being restated by a physician, and as such is not an expert opinion.

22. Futhermore, Dr. DiGregorio admits that he is unable to quantify this increased fear in any manner. FF ¶ 17 [U]nless there is a legally significant foundation for a plaintiff's increased risk of harm, a determination of damages for a plaintiff's fear becomes subjective. There must be some basis upon which a plaintiff's fear can be determined to be *reasonable." Sutcliffe v. G.A.F. Corp.*, 15 Phila. 339, 346 (C.P. Phila. 1987). When attempting to prove increased risk or fear, Pennsylvania law requires the party to establish the background levels, as well as the levels of the plaintiffs, so that the jury will be able to compare the two levels and have some reasonable basis to determine the alleged injuries. "One without the other is of no statistical or probative value since it would require sheer speculation. . . ." *Sutcliffe v. G.A.F. Corp.*, 15 Phila. 339, 345 (C.P. Phila. 1987). Dr. DiGregorio's inability to quantify Plaintiffs' fear or increased risk of harm renders his opinion to be of no probative value.

23. Therefore, Dr. DiGregorio's testimony concerning Plaintiffs' claims of increased fear must also be excluded pursuant to Rule 702 because his "diagnosis" lacks any reliable medical methodology and calls for sheer speculation.

C. *Medical Monitoring*

24. Dr. DiGregorio offers the opinion that Plaintiffs should be the subjects of a medical monitoring program in order to provide for the early detection of diseases.

FF ¶ 20. Defendants assert that this testimony should be excluded under Federal Rules of Civil Procedure 37(b) ("Rule 37(b)") as being untimely. Additionally, Defendants seek to exclude this opinion pursuant to Rule 702 because it is based on unreliable methodology.

1. *Rule 37(b)*

25. By Order dated June 4, 1991, this Court set March 17, 1992 as the deadline for Plaintiffs to file their Rule 26(b)(4) statements.[9] FF ¶ 1. At Dr. DiGregorio's final deposition on April 16, 1992, he testified that he had not developed a medical monitoring program for the Plaintiffs, nor had he been requested to do so. FF ¶ 20. However, two days later, Dr. DiGregorio submitted his Surveillance Program in which he outlined the monitoring that the Plaintiffs should undergo for the next twenty five years. FF ¶ 20.

26. Defendants claim that the late submission of this program, in contravention of the Court's Order, calls for its exclusion. Plaintiffs insist that the Rule 26(b)(4) letter dated March 17, 1992 expressly incorporated all facts and opinions of Dr. DiGregorio's prior testimony.[10] However, at his deposition, which occurred one month *after* the Court's deadline, Dr. DiGregorio still could not testify concerning his Surveillance Program because it had not been developed. FF ¶ 20. Since there is no prior testimony concerning the Surveillance Program, it is obvi-

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[9] The Order stated in relevant part: "2. On or before March 17, 1992, plaintiffs shall designate all trial expert witnesses and provide defendants with the substance of their trial testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4)."

[10] This letter stated in relevant part, "Additionally, G. John DiGregorio, M.D., Ph.D. was deposed in these cases. The defendants are fully aware of his curriculum vitae and his opinions regarding the above plaintiffs. Dr. DiGregorio may be called to testify on behalf of the above plaintiffs as to facts and opinions contained in his deposition testimony."

ous that such testimony could not be incorporated into Plaintiffs' March 17th letter. FF ¶ 20. It is not possible to incorporate prior testimony which has not been given.

27. Defendants further assert that admitting this newly developed evidence would greatly prejudice them. One day *after* submitting their own trial expert list, Defendants received a copy of Dr. DiGregorio's Surveillance Program.[11] FF ¶¶ 1, 20. Defendants contend that they will now have to obtain more experts to rebut Dr. DiGregorio's Surveillance Program. This, in turn, will require Defendants' experts to physically examine Plaintiffs, formulate their respective opinions and be deposed concerning these opinions. In addition, Dr. DiGregorio must be deposed concerning the specifics of his Surveillance Program.

28. There are four factors that a court should consider when deciding to exclude testimony for violation of an order: a) the prejudice or surprise of the party against whom the witness would have testified; b) the ability of that party to cure the prejudice; c) the extent to which allowance of the testimony would disrupt the order and efficiency of the trial; and d) the bad faith or willfulness in failing to comply with the court's order. *Myers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977).

29. Plaintiffs claim that the Defendants would not be surprised by this testimony because Dr. DiGregorio testified about a medical surveillance program on three instances, and the March 17th letter incorporated those statements. As previously stated, there was no incorpora-

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[11] The Courts' Order stated in relevant part: "On or before April 17, 1992, defendants shall designate all trial expert witnesses and provide the plaintiffs with the substance of their trial testimony and the basis for their opinions at the time of designation in accordance with Rule 26(b)(4)."

tion of prior testimony concerning the specifics of his Surveillance Program because it had yet to be developed as of the March 17th letter. Furthermore, on those prior occasions to which Plaintiffs refer, Dr. DiGregorio merely generalized as to medical monitoring programs. FF ¶ 20. At no time did he testify concerning the specifics of his Surveillance Program that would be presented at trial. In fact, Dr. DiGregorio stated that he had not been asked to develop such a program as of his 1992 deposition. FF ¶ 20. Furthermore, Dr. DiGregorio stated that he would have to review medical records of the Plaintiffs before he would be able to develop a program, and he had very few of the Plaintiffs' medical records at the time. FF ¶¶ 8, 20. He also stated that it would take him *two months* to develop such a program in the event that he was requested to do so. DiGregorio 1992 Dep. 35. However, *two days* after this deposition, Dr. DiGregorio submitted his Surveillance Program. FF ¶ 20.

30. Furthermore, Defendants attempted to question Dr. DiGregorio about this program at his final deposition, but Dr. DiGregorio was unable to render any testimony on the matter because the monitoring program had not been developed. FF ¶ 20. The Defendants are prejudiced in this matter because they have already submitted their list of experts as required by the Court's Order, but are being asked to further pursue this matter. Defendants would have to obtain additional experts to rebut Dr. DiGregorio's Surveillance Program, have these experts perform physical examinations of the Plaintiffs, review medical records, study the source of the alleged exposure, have their experts deposed concerning their opinions and further depose Dr. DiGregorio. All of this had to be completed in sixty days because the Court's Order stated that experts could not be deposed after June 17, 1992. FF ¶ 1.

31. Even though the Plaintiffs stated that Dr. DiGregorio would be available to testify on this matter at the Defendants' convenience, the Defendants would not

be able to cure this prejudice. There was merely too much required to properly respond to the Surveillance Program, and too little time in which to do it.

32. Furthemore, the Court's Order was dated June 4, 1991, which gave the Plaintiffs approximately nine and one-half months to develop a monitoring program. FF ¶ 1. This was obviously plenty of time, because it only took Dr. DiGregorio *two days* to develop the program once asked to proceed with it. FF ¶ 20.

33. Moreover, the allowance of this testimony would seriously disrupt the orderly and efficient procedure of this trial. A prolonged continuance would have to be granted to allow for the proper discovery of this matter. When one is allowed in excess of nine months to develop a medical monitoring program, choosing to wait until the last minute to develop such program does not provide reasonable justification for a continuance.

34. Finally, the Court finds that there is bad faith and willfulness on the part of Plaintiffs in failing to comply with the Court's Order. Plaintiffs were given nine and one-half months to develop a monitoring program. FF ¶ 1. The Plaintiffs' attorneys merely had to ask Dr. DiGregorio to proceed with the development of this program, and it is shown that two days later a completed program would be in their hands. FF ¶ 20. The Plaintiffs' attorney could have made this request at any point during the nine and one-half months between the issuance of the Court's Order and the March 17th deadline. Their lack of diligence in this matter constitutes a willful failure to comply with the Court's Order under *Pennypack*.

35. Based on the foregoing, Dr. DiGregorio's Surveillance Program is excluded pursuant to Rule 37(b).

2. *Rule 702*

36. Defendants further contend that Dr. DiGregorio's medical monitoring program should be excluded under Rule 702 because his methodology is unreliable.

37. To make out a claim for medical monitoring, it must be established that:

> 1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.
>
> 2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.
>
> 3. That increased risk makes periodic diagnostic medical examinations reasonably necessary.
>
> 4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

Paoli, 916 F.2d at 852.

38. In ruling upon this issue, the Court recognizes that "the appropriate inquiry is not whether it is reasonably probable that plaintiffs will suffer harm in the future, but rather whether medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease." *Paoli*, 916 F.2d at 851.

39. In formulating his opinion that medical monitoring was necessary, Dr. DiGregorio relied on Plaintiffs' beliefs that they were exposed to PCBs and that the Paoli Railyard was the source of the PCBs. FF ¶ 18. He did not perform any studies to examine the amount, duration or source of the alleged exposure. FF ¶¶ 16, 19. He admitted that he needed to perform studies concerning the type of exposure that the Plaintiffs were subject to as well as its source before he could render a final opinion. FF ¶¶ 14, 16, 29. As of his April 16, 1992 deposition, Dr. DiGregorio has not performed any of these tests. FF ¶ 29. Dr. DiGregorio's methodology in rendering this opinion is non-existent, and therefore completely unreliable. Mere assumptions and acceptance of a patient's beliefs do not form a reliable medical basis for an expert

opinion. As such, his opinion is unhelpful to the jury and excluded pursuant to Rule 702.

40. Furthermore, Dr. DiGregorio does not meet the standard required in this Circuit to testify as to the need for a medical monitoring program. This Circuit requires that it be shown, "to a *reasonable degree of medical certainty,*" that medical monitoring is "necessary in order to diagnose properly the warning signs of disease." *Paoli*, 916 F.2d at 851 (emphasis added). By merely relying on the statements of the Plaintiffs, failing to verify his preliminary diagnosis and failing to perform any tests concerning the amount and source of PCB exposure, Dr. DiGregorio's opinion is not "to a reasonable degree of medical certainty." *Id.*; FF ¶¶ 13-16, 18-19, 29.

41. As such, it is obvious that Dr. DiGregorio's opinion cannot aid in proving any of the elements needed to make a claim for medical monitoring. Because of his lack of proper methodology, Dr. DiGregorio is unable to show that "plaintiff[s] [were] significantly exposed to a hazardous substance," or that the exposure came from the Railyard, as is required under the first element of a claim for medical monitoring. *Paoli*, F.2d at 852. Furthermore, Dr. DiGregorio is unable to provide a reliable medical diagnosis that Plaintiffs' alleged injuries are a "proximate result of exposure" to PCBs. *Id.* As such, this testimony fails to aid in the proof of the second element of a cause of action in medical monitoring, namely that "[a]s a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease." *Id.*

42. Because Dr. DiGregorio's methodology was nonexistent, and as such unhelpful to the jury, his testimony concerning his Surveillance Program is excluded.

43. In addition, Defendants assert that the recent Pennsylvania Superior Court decision in *Marinari v. Asbestos Corp., Ltd.*, No. 90-1816, 1992 WL 165252 (Pa. Super. July 20, 1992) draws into question the validity of

a cause of action for medical monitoring in this state. In *Marinari,* the plaintiff-husband was diagnosed in 1983 as having pleural thickening. In 1987, he was diagnosed as having lung cancer. Plaintiffs, husband and wife, filed their complaint in 1987 seeking damages attributable to the cancer, which they claim was caused by asbestos exposure. The statute of limitations for personal injuries in Pennsylvania is two years. 42 Pa.C.S. § 5524(2). The trial court granted defendants' motion for summary judgment on the basis that the plaintiffs' complaint was barred by the statute of limitations. In reversing the trial court, the Superior Court stated that:

> Recovery can be had in a first action only for a disease which has already manifested itself from the exposure to asbestos and the natural, predictable progression, if any, of that disease. If additional injuries from a separate disease manifest themselves in the future, such injuries will support a second action."

Marinari, 1992 WL 165252 at *3. According to Defendants, *Marinari* has made Pennsylvania a two disease state.

44. Since Dr. DiGregorio's testimony has been excluded on other grounds, the Court is not faced with the issue of whether there exists a cause of action for medical monitoring in Pennsylvania in light of *Marinari.* Therefore, the Court does not rely on *Marinari* in excluding the testimony of Dr. DiGregorio.

45. I conclude that Dr. DiGregorio's testimony concerning a medical monitoring program is excluded pursuant to Rule 37(b) and Rule 702 as expressed above.

IV. CONCLUSION

For the foregoing reasons, I find that Dr. DiGregorio's testimony shall be excluded, and I shall accordingly enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS ORDER RELATES TO:

Cathlene Brown, et al. v. *SEPTA, et al.*	No. 86-7415
Celeste Brown, et. al. v. *SEPTA, et al.*	No. 86-7416
Christopher S. Brown, et al. v. *SEPTA, et al.*	No. 86-7414
Clemmon Brown, et al. v. *SEPTA, et al.*	No. 86-7420
Cloyd Brown, et al. v. *SEPTA, et al.*	No. 86-7421
Craig Brown et al. v. *SEPTA, et al.*	No. 86-7419
Curtis Brown, et al. v. *SEPTA, et al.*	No. 86-7422
Mary Retta Johnson, v. *SEPTA, et al.*	No. 86-7418
Margherita Barbetta, v. *SEPTA, et al.*	No. 86-7417

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendant's Motion *In Limine* to Exclude the Testimony of G. John DiGregorio, M.D., Ph.D., all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
Judge

APPENDIX III-D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

MEMORANDUM

R. F. KELLY, J. October 21, 1992

[As Amended February 1, 1993]

MOTION IN LIMINE TO EXCLUDE EVIDENCE OF ANIMAL STUDIES

This is another in a series of motions *in limine* filed by Defendants Monsanto, General Electric, Westinghouse, Septa, Budd, Amtrak and the City of Philadelphia to exclude evidence of animal studies pursuant to Rules 702 and 703 of the Federal Rules of Evidence. Hearings were held on this and the other motions filed by the parties on July 28, 29, 30, 31 and August 3, 1992. On August 7, 1992, all parties were given the opportunity to argue the motions *in limine* and the motion for summary judgment

now pending before this Court. From the testimony offered on this motion that those hearings, this Court makes the following:

FINDINGS OF FACT

1. Dr. Robert C. James is a toxicologist with a B.S. degree in chemistry and Ph.D. in pharmacology. He has in addition post-doctoral training at Vanderbilt University. James T. 73-75 [1]. Dr. James' post-doctoral work at Vanderbilt involved primarily research dealing with the metabolism or breakdown of chemicals and mechanisms for organ toxicity and primarily liver toxicity related to the metabolism of chemicals. These involved animal studies. After leaving Vanderbilt, Dr. James was the Director of Toxicology for a firm known as Ecology and Environment. That firm was involved in cleaning chemical spills and investigating abandoned waste sites or old spills. As a toxocologist, Dr. James did safety evaluation for field investigation teams and was part of the medical monitoring board that oversaw employees and checked the medical records when there were accidental exposure and evaluated those exposures. James T. 75-76. While he was with Ecology and Environment, Dr. James obtained his first experience in dealing with PCB problems. In 1983, Dr. James moved to the University of Arkansas where he took a position in the Division of Toxicology which was part of the Department of Pharmacology and Toxicology. There he taught graduate students in pharmacology and toxicology and also medical students. However, his primary position there was to conduct research. Currently, he is an Associate Professor at the center for Environmental and Human Toxicology at the University of Florida and is also President of TERRA, Inc. James T. 76-77. At the University of Florida he teaches and conducts research. TERRA, Inc. is a general toxicology consulting firm which conducts research, some of which

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[1] James T. refers to the testimony of Robert C. James given before this Court on July 31, 1992.

is funded by the federal government. It employs approximately 35 people, 10 or 12 of whom have Ph.Ds. Dr. James has authored approximately 50 scientific articles. James T. 78-79. For the last ten years, Dr. James has evaluated and reevaluated the PCB literature and maintains a personal library on this chemical containing over 2,000 scientific articles and 10 to 20 books touching on the various aspects of PCBs. James T. 80.

2. In toxicology, the term exposure is used to mean the eligibility to have contact with a particular chemical. The term dose is used to indicate the amount of chemical that is actually absorbed into the body. James T. 83.

3. The roots of exposure relating to contaminated soil would be incidental soil ingestion, dermal absorption or dermal exposure to soils in the inhalation of dust. The fact that a person may have been exposed to a chemical such as PCBs does not necessary indicate that that person has received a dose of PCBs. James T. 83-84.

4. Dose response relationship is the basic principle that toxicologists use to determine the safety or relative risk of a particular dose that a person has received. It is a mathematical or graphical understanding or the doses over which the chemical produces no effect, and the doses at which it produces whatever adverse effect to which toxicologists are concerned. There is a dose at which all substances will be harmful.

5. In animal studies, each test consists of a toxic endpoint that the researcher is looking at, so you are choosing a toxicity testing method to measure that. James T. 89.

6. There is a legitimate role for animal studies in determining potential human health effects of exposure to chemicals. Since one cannot test chemicals on human beings, it is necessary that you have some organism in which you can identify the possible doses and the possible

adverse effects that might occur in humans if they were to be exposed. James T. 89.

7. Some of the practical problems associated with animal studies are:

(a) Many test animals are bred to be sensitive to a particular type of response; James T. 91.

(b) Rodent tests are extremely sensitive so they identify a large number of chemicals as carcinogens in animals which are likely not to be carcinogens in humans; James T. 92.

(c) Dose is a major factor, "I mean we are pushing the dose of the chemical until we see a toxic effect." When dealing with humans on the other hand there is always an attempt to limit exposure so there will be no toxic effect. James T. 92-93.

(d) Animals have dramatically different physiology, biochemistry and metabolism pathways that break down the toxic chemicals so that, from species to species, there may be differences in bioactivation and detoxification; James T. 92, 93.

(e) Rats and mice are fed ad libitum, they are allowed to eat as much as they want. They become obese and it has been shown that because they are obese it increases the rate of tumors that have been observed; James T. 93.

(f) Test animals are ordinarily dosed with the chemical under study at the "maximally tolerated dose" which is the highest daily dose that the animal can sustain without having a decrease in body weight of more than ten percent. This may result in "metabolic overload" which refers to feeding test animals such high doses that their detoxification mechanism or physiologic processes are so overwhelmed that an abnormal alteration of metabolism is created and affects may be observed at those high doses which would not be observed at lower doses because the same conditions no longer exist in the animal. James T. 94-96.

8. Dr. James testified that approximately 1500 chemicals had been tested in animals and identified to be possible carcinogens in animals, whereas only about 30 chemicals have been identified as carcinogenic in humans. James T. 94. Dr. James further testified that with respect to the other 1,470 chemicals there is no epidemiological evidence that they are carcinogenic in humans, and for a number of them there is clear evidence that they are not carcinogenic in humans. James T. 141-42.

9. It is not valid to extrapolate from tests using high doses in which metabolic overloading occurs to circumstances involving low doses in which metabolic overloading does not occur because as you go down in dose you don't have to go down very far in dose to where you get a situation where the chemical is not causing any of the conditions that you see with the high doses that caused metabolic overloading. James T. 96-97.

10. Dr. James is familiar with the epidemiological studies, as to both morbidity and mortality, which investigate the human health effects of PCBs. In the studies of persons occupationally exposed to PCBs, for example, capacitor workers' dose levels reported are typically 100 to 1000 times higher than people whose body burdens are no different than the rest of the population that has ambient levels or concentrations in blood or fat. James T. 97.

11. The effects seen in maximally tolerated dosed PCB animal studies have not been observed in the studies of highly exposed workers. Therefore, it is not valid to use animal tests results as a basis for an opinion as to the causation of adverse health effects in persons such as the Plaintiffs in this case, who have much lower blood levels. James T. 99. This is true for cancer as well as other human health effects. James T. 99.

12. Animal studies can be validly used to test chemicals that humans have not been yet exposed to in order

to try to understand what possible effects might occur and under what dose. Therefore, before you have humans use a chemical, you would always want to do some basic animal research to identify what toxic effects might occur at various dose concentrations. You would need that in order to develop exposure guidelines so that people could work with those chemicals safely. James T. 101-02. It is Dr. James' opinion and the consensus in the scientific community that the only health effect observed in highly exposed worker populations to PCBs is chloracne. James T. 98, 105-06; *see also* Kimbrough, "Human Health Effects of Polychlorinated Biphenyls [PCBs and Polychlorinated Biphenyls] (PCBs)" American Review of Pharmacology Toxicology, 27 A. Rev. Pharmacal. Toxicol. 87(1987).

13. Dr. James expressed his opinion that it would not be reasonable for a scientist to rely upon animal studies to establish causation in humans in the face of such contradictory epidemiological evidence in studies of humans exposed to PCBs; that it would be an improper and unreliable use of animal data; that it would be improper scientific methodology; and that it would be confusing or misleading. James T. 106-07.

CONCLUSIONS OF LAW

1. Rules 702 and 703 of the Federal Rules of Evidence govern the admissibility of an expert opinion. The Third Circuit has incorporated these rules into a two-prong test for determining whether an opinion is admissible: (1) The opinion must be based upon facts and data of a type "reasonably relied upon by experts in a particular field," Federal Rule of Evidence 703 ("Rule 703"), 703, and (2) The opinion must "assist the trier of fact to understand the evidence or to determine a fact in issue." Federal Rule of Evidence 702 ("Rule 702").

2. In the case of *In re Japanese Electrocinc Products Antitrust Litigation,* 723 F.2d 238 (3d Cir. 1983), *rev'd*

on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574 (1986), the court warned that courts should not admit expert testimony without limitation. Rather, expert testimony should be presented to a jury only after sufficient inquiry into its reliability and foundation. The *Japanese Electronic* court stated that in determining for purposes of Rule 703 whether the informational basis of an expert opinion is of a type reasonably relied upon by experts in the field, "the proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be." 723 F.2d at 276.

3. In addition to the requirement that the evidence must be of a type reasonably relied upon by experts, Rule 702 requires that the data also be used in a "reliable manner." As stated by the Third Circuit in *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), the court must determine that the use of the evidence will assist the trier of fact to determine the evidence or determine a fact in issue. *Downing* held that the "helpfulness" requirement in Rule 702 "implies a quantum of reliability beyond that required to meet a standard of bare logical relevance." *Id.* at 1235.

4. When a court must rule on the admissibility of scientific evidence which is not judicially noticed, it must determine: (1) the soundness and reliability of the process or technique used in generating the evidence, (2) the possibility that admitting the evidence will overwhelm, confuse, or mislead the jury, and (3) the proffered connection between the scientific research or test result to be presented and the particular factual issues in the case. *Id.* at 1237.

5. Even if the Court determines that the data used by the expert is of a type reasonably relied upon by experts in rendering an opinion. It must still address the reliability or general acceptance of an expert's *methodology. DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990).

6. In excluding animal evidence as being "not persuasive" in the case of *In re "Agent Orange" Product Liability Litigation,* 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd,* 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi v. Dow Chemical Co.,* 487 U.S. 1234 (1988), the court stated that "there is no evidence that plaintiffs were exposed to the far higher concentrations involved in both the animal and industrial exposure studies. The animal studies are not helpful in the instant case because they involve different biological species. They are of so little probative force and are so potentially misleading as to be inadmissible." 611 F. Supp. at 1241 (citations omitted).

7. In a *Bendectin* case, the first circuit in *Lynch v. Merrell National Laboratories,* 646 F. Supp. 856, (1986) *aff'd,* 830 F.2d 1190 (1st Cir. 1987), stated that "It is also difficult to extrapolate findings from animal studies to human studies because of the large dosage used in the animal studies. . . . [A]lmost any substance can be shown to be teratogenic at some dose in some species." 646 F. Supp. at 865.

8. In *Viterbo v. Dow Chemical Co.,* 826 F.2d 420 (5th Cir. 1987), where plaintiff sought to admit expert testimony based on animal studies that a pesticide caused a variety of ailments, including depression, neurosis and hypertension, plaintiff's expert relied upon a study in which rats exposed to the pesticide developed cancerous tumors and died. The court held the evidence insufficient to provide support for an opinion on causation because the expert acknowledged that the effects of chemicals differ between humans and rats, there was no evidence that plaintiff and the rats received comparable doses, and plaintiff's symptoms were different from those suffered by the rats.

9. In *Selwood v. Oxford Chemicals, Inc.,* No. 90-1048 (M.D. Pa. June 28, 1991), *aff'd,* No. 91-5619 (3d Cir.

February 21, 1992), a pesticide exposure case, Judge Kosik excluded expert testimony premised on animal studies under Rule 702 because those studies are "grossly conjectural" and therefore could not assist the trier of fact.

10. I find that experts in science and medicine rely upon animal studies in determining potential human health effects of exposure to chemicals. Since chemicals cannot be tested on human beings, it is necessary that there be some organism in which scientists can identify the possible doses and the possible adverse effects that might occur in humans if they were to be exposed. However, I further find that experts in science and medicine do not reasonably rely upon animal data to predict causation of human health effects when the data is contradicted by significant epidemiological data in humans.

11. I find that animal studies are of limited reliability when attempting to relate those studies to humans because:

(a) Many test animals are bred to be sensitive to a particular type of response; James T. 91.

(b) Rodent tests are extremely sensitive so they identify a large number of chemicals as carcinogens in animals which are likely not to be carcinogens in humans; James T. 92.

(c) Dose is a major factor, "I mean we are pushing the dose of the chemical until we see a toxic effect." When dealing with humans on the other hand there is always an attempt to limit exposure so there will be no toxic effect. James T. 92-93.

(d) Animals have dramatically different physiology, biochemistry and metabolism pathways that break down the toxic chemicals so that, from species to species, there may be differences in bioactivation and detoxification; James T. 92, 93.

(e) Rats and mice are fed ad libitum, they are allowed to eat as much as they want. They become obese and it has been shown that because they are obese it increases the rate of tumors that have been observed; James T. 93.

(f) Test animals are ordinarily dosed with the chemical under study at the "maximally tolerated dose" which is the highest daily dose that the animal can sustain without having a decrease in body weight of more than ten percent. This may result in "metabolic overload" which refers to feeding test animals such high doses that their detoxification mechanism or physiologic processes are so overwhelmed that an abnormal alteration of metabolism is created and affects may be observed at those high doses which would not be observed at lower doses because the same conditions no longer exist in the animal. James T. 94-96.

12. I find that the use of animal studies data as a basis for an opinion as to causation of adverse health effects in humans when that data is contradicted by significant epidemiological data in humans, is an unreliable use of such data. I find further that such a use of that data would tend to mislead or confuse the jury and would be of no assistance to the jury in deciding the issues in this case.

13. I also find that animal studies of PCBs are not relevant to prove exposure to PCBs or causation of adverse health effects in the Plaintiffs and that such evidence is irrelevant and inadmissible under Rule 402 of the Federal Rules of Evidence.

I therefore issue the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, the Defendants' Motion *In Limine* to Exclude Evidence of Animal Studies is GRANTED. Plaintiffs are prohibited from presenting testimony, evidence or statements to the jury concerning or relying upon animal studies to predict causation of human health effects.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX III-E

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
Goerge Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

MEMORANDUM

R. F. KELLY, J. October 21, 1992

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFFS' PERSONAL INJURY CLAIMS

Defendants General Electric Co., Monsanto Co., Westinghouse Electric Corp., Southeastern Pennsylvania Transportation Authority, National Railroad Passenger Corporation, The Budd Co., and the City of Philadelphia have filed a Motion for Summary Judgment as to all of Plaintiffs' personal injury claims. The Plaintiffs involved in this motion are all present or former residents of the neighborhood adjacent to the Paoli Railyard ("the Yard") to distinguish them from plaintiffs who were *employed* at the Yard. This motion concerns a total of eighteen consolidated actions involving thirty-two Plaintiffs or Plaintiffs' decedents (hereinafter "Plaintiffs"), who claimed to have suffered personal injuries as a result of alleged exposure to polychlorinated biphenyls ("PCBs") from the Yard. Plaintiffs seek recovery for, (1) physical injuries caused by PCBs; (2) the increased risk of future illness; (3) fear of emotional distress; (4) the cost of a medical monitoring or surveillance program. Although Plaintiffs have now abandoned their claims for increased risk, they continue to press their claims for recovery on the other three grounds.

In November 1988, this Court granted summary judgment in favor of Defendants on Plaintiffs' personal-injury claims. *In re Paoli R.R. Yard PCB Litigation*, 706 F. Supp. 358 (E.D. Pa. 1988). The Court of Appeals reversed that judgment and remanded the actions for further proceedings. *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991).

On remand, by Order dated June 4, 1991, we established a discovery schedule that required Plaintiffs to

identify their trial experts and to disclose the substance of those experts' opinions by March 17, 1992. Defendants were required to produce the same information for their trial experts by April 17, 1992. This same Order also allowed the parties to have until June 17, 1992 to depose expert witnesses. At Plaintiffs' request, that deadline was later extended to June 24, 1992. The June 4, 1991 Order also set a firm trial date for August 3, 1992. We severed, and deferred for a later trial, three other actions involving individuals who had worked at the Yard and who asserted claims under the Federal Employers Liability Act.

The list of expert witnesses identified by Plaintiffs in March 1992 was substantially different from those involved in the case at the time of the 1988 summary judgment and appeal. Certain Plaintiffs represented by the Kohn, Nast and Klehr, Harrison law firms (the "Kohn/Klehr Plaintiffs") named three experts on issues relevant to their personal-injury claims: (1) Melvyn Kopstein, Ph.D., was designated to testify about the Paoli residents' "opportunities for exposure" to PCBs from the Yard; (2) Ian C.T. Nisbet, Ph.D., was designated to testify about Plaintiffs' exposure to PCBs; and (3) Janette Sherman, M.D., was designated to testify that Plaintiffs' alleged injuries were caused by their exposure to PCBs and that Plaintiffs require medical monitoring to detect and treat future PCB-related illnesses.

The Plaintiff in *Reid v. Septa, et al.* No. 87-5304 did not designate any expert witness in March 1992 as required by the June 4, 1991 scheduling Order.[1]

In their joint pretrial memorandum filed July 17, 1992, the Kohn/Klehr and Hanes Plaintiffs designated three *additional* trial experts—Deborah Barsotti, Ph.D., Benjamin Calesnick, M.D., and Arthur Zahalsky, Ph.D. Al-

[1] See this Court's memorandum regarding Defendants' Motion to Preclude Expert Testimony of Dr. Harry Shubin.

though those individuals had offered opinions on Plaintiffs' behalf in 1988, they had not been designated as trial experts, nor had the substance of their opinions been disclosed, in accordance with this Court's June 4, 1991, Order. Defendants had deposed Drs. Barsotti and Zahalsky in 1988 (they had never deposed Dr. Calesnick), but they did not depose these individuals during the expert discovery period following the remand of these cases. Plaintiffs' pretrial memorandum also listed as a "fact witness" William J. Nicholson, Ph.D., who in 1988 had offered opinions on Plaintiffs' behalf as a *expert* witness.[2]

By Order dated June 3, 1992, this Court set June 25, 1992, as the deadline for the parties to submit motions *in limine* and dispositive motions. On that date, Defendants filed, *inter alia,* separate motions *in limine* to exclude the opinions of Drs. Kopstein, Nisbet, Sherman, Schecter, and DiGregorio under Federal Rules of Evidence 702, 703, and 403, and the instant motion for summary judgment on Plaintiffs' person-injury claims.[3] On July 28, 29, 30, and 31, and August 3, 1992, this Court conducted an evidentiary hearing on the motions *in limine.* Among Plaintiffs' experts, Drs. Kopstein, Nisbet, and Sherman testified at that hearing. At the conclusion of the hearing, this Court continued the trial date pending disposition of

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[2] See this Court's memorandum regarding Defendants' Motion to Preclude the Testimony of Drs. Calesnick, Barsotti, Zahalsky, Nicholson, and Jenkins.

[3] Defendants also filed motion *in limine* to exclude, and to bar Plaintiffs' experts from testifying about, three categories of evidence: (1) studies purporting to show adverse effects of PCB exposure in animals; (2) evidence concerning the alleged health effects of certain chemicals (including dioxins and dibenzofurans) other than PCBs that are sometimes present in trace amounts in transformer fluid but as to which Plaintiffs have presented no proof of their own exposure; and (3) evidence concerning incidents in Japan and Taiwan (known as "Yusho" and Yu Cheng," respectively) in which large numbers of individuals ingested rice oil that had been contaminated with PCBs and dibenzofurans.

the parties' motions. Those motions have now been decided.

I have excluded the opinion testimony of Janette D. Sherman, M.D. for the reasons set forth in my memorandum re: Motion to Exclude the Opinion Testimony of Janette D. Sherman, M.D. Because of that ruling, the following Kohn/Klehr residential Plaintiffs are without expert testimony with regard to medical causation:

Bessie Cunningham	No. 87-5269
Matthew Cunningham	No. 87-5269
Patricia Ingram	No. 86-7561
John Ingram, Sr.	No. 86-7561
John Ingram, Jr.	No. 86-7561
April Ingram Robinson-Ray	No. 86-7561
Patricia Burrell	No. 86-2235
George Burrell	No. 86-2235
Amber Burrell	No. 86-2235
Monica Hilton	No. 86-2235

Twelve of the Kohn/Klehr Plaintiffs *never* had expert testimony as to medical causation. They are:

Mabel Brown	No. 86-2229
Theresa Butler	No. 87-2874
William Butler	No. 87-2874
Bryan Jackson	No. 87-2874
Wallace Cummins	No. 86-2669
Harvey Jones	No. 86-5277
Louise Jones	No. 86-5277
Mary Alice Knight	No. 87-0712
Allen Simpson	No. 87-2874
Donald Simpson	No. 87-2874
Karen Simpson	No. 87-2874
Marvin Simpson	No. 87-2874

For the reasons set forth in the memorandum relating thereto, I have excluded the opinion testimony of Ian C.T. Nisbet, Ph.D. as to exposure to PCBs. Because of that ruling, five of the Kohn/Klehr Plaintiffs are without expert testimony as to exposure. They are:

Bessie Cunningham	No. 87-5269
Matthew Cunningham	No. 87-5269
Amber Burrell	No. 86-2235
Priscilla Burrell	No. 86-2235
Patricia Ingram	No. 86-7561

Seventeen of the Kohn/Klehr Plaintiffs *never* proffered expert testimony as to exposure to PCBs. They are:

Mabel Brown	No. 86-2229
George Burrell	No. 86-2235
Theresa Butler	No. 87-2874
William Butler	No. 87-2874
Monica Hilton	No. 86-2235
Bryan Jackson	No. 87-2874
Wallace Cummins	No. 86-2669
John Ingram, Jr.	No. 86-7561
John Ingram, Sr.	No. 86-7561
April Ingram Robinson-Ray	No. 86-7561
Harvey Jones	No. 86-5277
Louise Jones	No. 86-5277
Mary Alice Knight	No. 87-0712
Allen Simpson	No. 87-2874
Donald Simpson	No. 87-2874
Karen Simpson	No. 87-2874
Marvin Simpson	No. 87-2874

For the reasons set forth in the memoranda dealing with the motions *in limine* to exclude the testimony of G. John DiGregorio, M.D. and Arnold J. Schecter, M.D., M.P.H., I have excluded their opinion testimony. For that reason, all nine of the Bruce Hanes' Plaintiffs are without expert testimony as to medical causation and exposure to PCBs. Those nine Plaintiffs are:

Cathlene Brown	No. 86-7415
Celeste Brown	No. 86-7419
Christopher Brown	No. 86-7414
Clemmon Brown	No. 86-7420
Cloyd Brown	No. 86-7421

Craig Brown	No. 86-7416
Curtis Brown	No. 86-7422
Mary Johnson	No. 86-7418
Margherita Barbetta	No. 86-7417

For the reasons set forth in the memorandum regarding Defendants' Motion To Preclude Expert Testimony of Harry Shubin, M.D., the Plaintiff in *Reid v. Septa* is without expert testimony as to medical causation and exposure to PCBs.

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment shall be entered in favor of the moving party where it appears "that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." The standard for granting summary judgment "mirrors the standard for a directed verdict." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). In response to a motion for summary judgment, the non-moving party cannot simply rest on the assertions in his pleadings; rather, he must make a sufficient showing to establish a genuine issue of fact on those elements with respect to which he has the burden of proof. *Celotex Corp.*, 477 U.S. at 323.

As set forth in the findings of fact and conclusions of law in support of the Orders excluding Plaintiffs' expert testimony, the opinions of Drs. Nisbet, Sherman, Schecter, and DiGregorio are inadmissible under Rules 702, 703, and 403 of the Federal Rules of Evidence.[4] Inadmissible evidence is not properly part of the summary judgment record and cannot create a genuine issue of material fact sufficient to block summary judgment. *See In re Paoli,*

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[4] In addition, as set forth in the relevant findings of fact and conclusions of law, Plaintiffs' evidence regarding animal studies, dioxins and other purported chemical components of transformer fluid, and the Yusho and Yu Cheng incidents is inadmissible and cannot form the basis for expert opinions in these cases.

916 F.2d at 862; *Fowle v. C&C Cola*, 868 F.2d 59, 67 (3d Cir. 1989).

I have not considered the opinions of Drs. Barsotti, Zahalsky, Calesnick, and Nicholson who were not identified as trial witnesses until the Kohn/Klehr and Hanes Plaintiffs filed their joint pretrial memorandum. Plaintiffs knew that they were required to designate their trial experts by March 17, 1992, but they failed to do so. Moreover, Defendants would be seriously prejudiced if they were required to defend against the opinions of the newly identified experts at this late date.

To prove a prima facie case Plaintiffs must establish the following elements: (1) that Defendants released PCBs into the environment; (2) that Plaintiffs somehow ingested those PCBs into their bodies; (3) that Plaintiffs have an injury; and (4) that PCBs are the cause of the injury. *In re Paoli*, 916 F.2d at 860. Plaintiffs have no competent expert evidence on the crucial issues of exposure and causation. Without such expert testimony, Plaintiffs cannot prove elements 2, 3, and 4.

Also in, *In re Paoli*, 916 F.2d at 852 the court indicated its approval of the case of *Merry v. Westinghouse Electric Corp.*, 684 F. Supp. 847 (M.D. Pa. 1988) as follows:

> "We agree with *Merry*, and predict that the Supreme Court of Pennsylvaia would follow the weight of authority and recognize a cause of action for medical monitoring established proving that:
>
> 1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.
>
> 2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.

3. that increased risk makes periodic diagnostic medical examinations reasonably necessary.

4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

These factors would, of course, be proven by competent expert testimony, *see Ayers*, 106 N.J. at 606, 525 A.2d at 312."

There is no reason why the requirement of proof by *competent expert testimony* should be confined to the issue of medical monitoring.

For the foregoing reasons, I enter the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
Goerge Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

ORDER

AND NOW, this 21st day of October, 1992, Summary Judgment is hereby entered in favor of all Defendants against all Plaintiffs in the above captioned matter.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa. et al.*	No. 86-7416
Margherita Barbetta, v. *Septa, et al.*	No. 86-7417
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Mary Retta Johnson, v. *Septa, et al.*	No. 86-7418
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422

MEMORANDUM

R. F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE THE TESTIMONY OF DR. ARNOLD J. SCHECTER, M.D.

Defendants moved to preclude the testimony of Plaintiffs' expert Arnold J. Schecter, M.D. on the grounds that Dr. Schecter's testimony lacks the requisite factual foundation and the application of reliable scientific methodology for admissibility under Rules 702 and 703 of the Federal Rules of Evidence. Defendants also argue that Dr. Schecter fails to quantify Plaintiff's alleged increased risk of future illness as required under Pennsylvania law.

From the pleadings, depositions and arguments of counsel, I make the following:

FINDINGS OF FACT

1. On June 4, 1991, this Court directed that Plaintiffs designate all trial expert witnesses and provide Defendants with the substance of their testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4) by March 17, 1992.

2. In compliance with that Order, Plaintiffs designated Dr. Arnold J. Schecter as an expert witness and provided his report dated March 16, 1992. In that report, he opined that exposure to PCBs and related chemicals caused certain adverse health effects and that Plaintiffs have reasonable fear of adverse health effects as a result of exposure to PCBs and "coexisting chemicals."

3. At the court hearing on this motion, counsel for Plaintiffs withdrew Dr. Schecter as an expert for the purpose of testifying that Plaintiffs have an increased risk of adverse health effects stating "he may be proffered at time of trial to testify that the Plaintiffs' fear of harm is reasonable . . . ." July 28, 1992 Hearing at 184.

4. Dr. Schecter is offered therefore as an expert witness only as to Plaintiffs' allegation that they suffer from psychological ailments, *i.e.*, fear of future adverse health effects as a result of PCB exposure. July 28, 1992 Hearing at 167-68, 185-86.

5. Dr. Schecter admitted during his deposition that he is unable to offer any opinion as to whether any Plaintiff actually has a fear of future illness or other form of emotional distress. Schecter Dep. 146-47.[1] Dr. Schecter is able to say only that if Plaintiffs do in fact have any such fears, then those fears are reasonable. Schecter Dep. 29; Dr. Schecter's Report.

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[1] Schecter Dep. refers to the deposition of Dr. Arnold J. Schecter taken on June 9 and 10, 1992.

6. Dr. Schecter admitted that he cannot quantify Plaintiffs' risk of contracting future illnesses and does not know the difference, if any, between any Plaintiff's risk of future illness and that of the general population. Schecter Dep. 69-70.

7. Dr. Schecter did not meet Plaintiffs, did not talk to Plaintiffs, did not talk to Plaintiffs' physicians, and did not conduct physical or psychological examinations of Plaintiffs. Schecter Dep. 101-02, 104-05, 147. The sole basis for Dr. Schecter's testimony about any of these plaintiffs is a single conversation with Plaintiffs' counsel during which Plaintiffs' counsel selected and read to Dr. Schecter certain unspecified portions of the deposition testimony of certain unknown Plaintiffs. Schecter Dep. 15, 101-02. Dr. Schecter also refers to reviewing reports in the scientific literature that PCB exposure causes certain illnesses in laboratory animals and that PCBs are believed to cause these illnesses in human populations. Schecter Dep. 34; Dr. Schecter's Report.

8. Dr. Schecter testified that his routine methodology in evaluating his patients includes obtaining complete medical histories, conducting physical examinations, and performing various tests as needed. Schecter Dep. 117-18. In reaching his opinions for this litigation, Dr. Schecter did not follow that stated methodology. Schecter Dep. 147.

9. Because Dr. Schecter cannot quantify or describe in any way the extent of Plaintiffs increased risk of future illnesses, if any, he cannot opine as to the reasonableness of any fears that might be held by Plaintiffs.

10. Whether damages should be awarded for *fear* of future illness is directly related to the issue of *risk* of future illness. If Dr. Schecter cannot quantify the extent of Plaintiffs' increased risk of future illnesses, he may not give his opinion as to the reasonableness of Plaintiffs' fear of such future illnesses.

CONCLUSIONS OF LAW

1. In order to evaluate the admissibility of Dr. Schecter's testimony, this Court has conducted an *In Limine* Evidentiary Hearing as contemplated by *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985). A record has been produced that is sufficient to evaluate Dr. Schecter's proposed testimony under Rule 702 and 703 of the Federal Rules of Evidence.

2. Rule 702 of the Federal Rules of Evidence ("Rule 702") provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

3. Rule 702 authorizes the admission of expert testimony so long as it is (1) rendered by a qualified expert and (2) helpful to the trier of fact. *DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). The helpfulness requirement contains the proposition that expert testimony that is based on unreliable methodology is unhelpful and therefore excludable. *DeLuca*, 911 F.2d at 954.

4. Rule 703 of the Federal Rules of Evidence ("Rule 702") focuses on the reliability of the facts of data upon which the expert has based his opinion. Rule 703 provides:

> The facts or other data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by the experts in a particular field

> in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

5. Both Rule 702 and Rule 703 require that expert testimony be supported by an adequate factual foundation. *In re "Agent Orange" Product Liability Litigation*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi v. Dow Chemical Co.*, 487 U.S. 1234 (1988).

6. Dr. Schecter admitted at his deposition that he cannot quantify Plaintiffs' risk of contracting future illnesses and does not know the difference, if any, between any Plaintiff's risk of future illness and that of the general population. If Dr. Schecter cannot answer the foregoing questions then he has no basis for an opinion as to the reasonableness of Plaintiffs' fear of future ill health. Dr. Schecter's opinion as to the reasonableness of Plaintiffs' fears is nothing more than an empty conclusion.

7. The lack of any factual foundation renders Dr. Schecter's opinion as to the reasonableness of Plaintiffs' fears unreliable and completely speculative. Under Pennsylvania law, "[U]nless there is a legally significant foundation for a plaintiff's increased risk of harm, a determination of damages for a plaintiff's fear becomes subjective. There must be some basis upon which a plaintiff's fear can be determined to be *reasonable*." *Sutcliffe v. G.A.F. Corp.*, 15 Phila. 339, 346 (1987). As in the *Sutcliffe* case, Plaintiffs' expert can offer no reasonable quantification of the increased risk of harm, if any, suffered by any of the Plaintiffs in this litigation. Therefore, there is no factual basis upon which Dr. Schecter can base his conclusion that Plaintiffs' fears are reasonable.

I therefore issue the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al v. *Septa, et al.*	No. 86-7421
Custis Brown, et al. v. *Septa, et al.*	No. 86-7422

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Dr. Schecter, Plaintiff's response thereto, the record and oral arguments of counsel, it is hereby ORDERED that said Motion is GRANTED. I conclude that Dr. Schecter did not follow a reasonable methodology in reaching his diagnoses, that his opinions were not based on any factual foundation and that he did not rely on data of a type reasonably relied upon by experts in the field when forming his opinions. Dr. Schecter's testimony is hereby excluded from the trial of this case under Rules 702 and 703 of the Federal Rules of Evidence.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO ALL CASES

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Plaintiffs' Expert, Melvyn Kopstein, Ph.D., all responses thereto, and a hearing on said matter, it is hereby ORDERED that said Motion is DENIED. This Court shall permit Dr. Kopstein to testify regarding Plaintiffs' "opporunities for exposure" to PCBs. Therefore, his testimony shall not be excluded on this basis.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *SEPTA, et al.*	No. 86-2235
John Ingram, et al. v. *SEPTA, et al.*	No. 86-7561
Andre Williams v. *SEPTA, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *SEPTA, et al.*	No. 87-5269

MEMORANDUM

R.F. KELLY, J. October 21, 1992

This is a toxic tort case brought by individuals who maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") from having either worked in or lived adjacent to the Paoli Railyard in Paoli, Pennsylvania. This Court held hearings on July 28, 29, 30, 31 and August 3 and 7, 1992 eliciting testimony and argument on the numerous motions *in limine* and dispositive motions filed in this action.

MOTION IN LIMINE TO EXCLUDE RESULTS OF ANALYSES PERFORMED BY ELI ECO LOGIC LABORATORIES, INC.

Defendants have filed this Motion *In Limine* to exclude all testimony concerning the results of PCB cogener specific analyses of six Plaintiffs performed in May of 1992 by ELI Eco Logic Laboratories, Inc. ("Eco Logic"). Defendants argue that the Eco Logic analyses should be excluded because the results are scientifically unreliable and not data which is reasonably relied upon by experts in the field.

In support of its motion, Defendants presented the testimony of James C. Peterson, Ph.D. ("Dr. Peterson") and his affidavit. Defendants moved into evidence the deposition of Ian C.T. Nisbet, Ph.D. ("Dr. Nisbet") who based many of his opinions on the Eco Logic analyses. In response to Defendants' motion, Plaintiffs presented the testimony and affidavit of Richard F. Gierczak ("Mr. Gierczak") who is an employee of Eco Logic. Plaintiffs also presented the testimony of Dr. Nisbet.

Upon consideration of Defendants' Motion *In Limine* to Exclude the Results of Analyses Performed by Eco Logic, all responses thereto, the hearing and deposition testimony presented to this Court, and all exhibits admitted into evidence at the hearing, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Plaintiffs offered Dr. Nisbet as an expert in assessing the exposure of Plaintiffs to PCBs. Dr. Nisbet concluded that several of the Plaintiffs "were sufficiently exposed [to PCBs from the Paoli Rail Yard] . . . to lead to the expectation that they would suffer adverse health effects as a result of [th]eir exposure." March 16, 1992 Report of Dr. Nisbet at 2, 6 (Attached as Exhibit 12 to Defendants' *in limine* Exhibit 22) ("Nisbet Report").

2. Dr. Nisbet's opinion is based in part upon back-calculations that he performed of the 1992 Eco Logic results. July 30, 1992 Hearing Testimony of John Whysner, Ph.D. ("Whysner T") at 23; July 30, 1992 Hearing Testimony of Dr. Nisbet ("Nisbet T.") at 86. In May of 1992, six Plaintiffs' PCB blood levels were tested by Eco Logic which is located in Canada. Whysner T. 22. Dr. Nisbet estimated Plaintiffs' PCB blood levels as of 1986 based upon back-calculations of Plaintiffs' 1992 PCB blood levels recorded by Eco Logic. Nisbet T. 86-87, 102.

3. At the *in limine* hearing, Defendants presented the testimony of Dr. Peterson in support of its motion to exclude the analyses performed by Eco Logic. July 29, 1992 Hearing Testimony of Dr. Peterson ("Peterson T.").

4. Dr. Peterson received his bachelor's degree in Chemistry from North Park College, Chicago, Illinois in 1972. Peterson T. 185. He received a Ph.D. in Analytical Chemistry from the University of Maryland in 1980. Dr. Peterson did his post-doctoral training in Analytical Chemistry at Ecole Polytechnique in France from 1980 to 1982. *Id.*

5. After this training, Dr. Peterson was Supervisor of the Virginia Division of Consolidated Laboratory Services in Richmond, Virginia which is an organization that analyzes trace organics in all types of environmental samples using mostly gas chromatography/mass spectrometry. *Id.*

6. In 1985, Dr. Peterson became Director of Research and Development at Pacific Toxicology Laboratories in Los Angeles, California and has continued in that position for the past seven years. *Id.* at 186. His responsibilities as Director of Research and Development include ensuring that the technical aspects of the laboratory are functioning properly, developing methodologies for gas chromatography/mass spectrometry and gas chromatography/

electron capture analyses, training technologists in the performance of those methodologies and reviewing laboratory results. *Id.* at 186-87.

7. Dr. Peterson routinely analyzes serum samples in adipose tissue for the presence of PCBs in his employment with Pacific Toxicology Laboratories. *Id.* He has analyzed or supervised the analyses of over 30,000 samples for the presence of PCBs. *Id.* Approximately 500 of the 30,000 samples were analyzed by the congener specific analysis. *Id.* at 188.

8. Defendants offered Dr. Peterson as an expert in Analytical Chemistry. Plaintiffs did not challenge Dr. Peterson's qualifications. *Id.* at 188.

9. Dr. Peterson reviewed the depositions of Dr. Nisbet and two Eco Logic employees, Mr. Resch and Mr. Gierczak, and the materials produced by Eco Logic which included information regarding the analytical procedure employed and the data itself. *Id.* at 188-89. Dr. Peterson spent approximately 12 hours reviewing Eco Logic's analytical procedures and the data itself. *Id.* at 189.

10. At the *in limine* hearing, Plaintiffs presented the testimony of Mr. Gierczak in response to Defendants' Motion to Exclude the Analyses Performed by Eco Logic. July 31, 1992 Hearing Testimony of Mr. Gierczak ("Gierczak T.").

11. Plaintiffs offered Mr. Gierczak as an expert in Analytical Chemistry. Defendants challenged Mr. Gierczak's qualifications. Gierczak T. 158.

12. Mr. Gierczak obtained a bachelor's degree in 1984 and master of science degree in Medical Sciences in 1988 from McMaster University in Hamilton, Ontario. *Id.* at 152. In connection with obtaining his master's degree, Mr. Gierczak did original research which involved looking at the metabolism of a specific equine estrogen. *Id.* at 153. Mr. Gierczak is currently an employee of Eco Logic and has worked at Eco Logic for about two and half

years. *Id.* at 154-55. Eco Logic is a scientific consulting firm. *Id.* at 155. About 90% of the work that Mr. Gierczak performs for Eco Logic is litigation-related. *Id.* at 188.

13. Mr. Gierczak's formal training in Analytical Chemistry consists of courses that he took as an undergraduate. *Id.* at 241. He has analyzed approximately 50 samples using the PCB congener specific analysis for the purposes of "method development." *Id.* at 189-90. Eco Logic's report in this case of the six Plaintiffs' PCB blood levels was the first report ever issued regarding PCB congener specific analyses of human blood samples. *Id.* at 190-92.

14. On his curriculum vitae, Mr. Gierczak listed the World Health Organization as recent client experience. However, he admitted that the World Health Organization was only a resource and that Eco Logic did not "do anything for the World Health Organization." *Id.* at 200-02.

15. Plaintiffs' blood samples were received by Eco Logic on or about March 13, 1992. Eco Logic reported the results of its analyses performed on these samples three months later on June 15, 1992. *Id.* at 209.

16. Eco Logic failed to provide a written laboratory protocol describing the technique that was performed. Peterson T. 189-90. A written laboratory protocol is a "step-by-step explanation to the technologist performing the test, how to perform the test in great detail. It also includes the extraction process, clean-up, preparation of the samples, the analytical instrumentation procedures, as well as quality assurance requirements to perform the test." *Id.* at 190. The purpose of having a written laboratory protocol is to ensure that the analysis is performed the same way each time. *Id.* at 192-93. Also, the written protocol is used by outside scientists or analytical chemists to review the results and evaluate the data. *Id.* at

193. Dr. Peterson stated that a written laboratory protocol is something that every reliable laboratory would have. *Id.* at 190. It is accepted practice to have such a protocol, and a written laboratory protocol is essential, particularly in a complex analysis. *Id.* at 192.

17. Congener specific analysis of PCBs is the most complex analytical chemistry procedure that Dr. Peterson has encountered. *Id.* at 190. It takes approximately six or seven days to perform this type of analysis. *Id.* at 191-92. There are many different PCB components which are called "congeners" in a human blood sample or an environmental PCB mixture. The congener specific analysis is a technique in which individual congeners of a PCB mixture are quantitated and reported. *Id.* at 187-88.

18. In response to requests for a written description of the technique that Eco Logic used in performing its analyses of Plaintiffs' blood samples, Eco Logic eventually provided to Defendants a brief summary of the steps taken in the analytical process. *Id.* at 193. "But it wouldn't qualify as a written laboratory protocol as such, which would be used in a laboratory." *Id.* The summary included about one page concerning sample extraction and clean-up and approximately six pages of analytical instrumentation descriptions. *Id.* Mr. Gierczak acknowledged that Eco Logic did not have a written laboratory protocol for the performance of PCB congener specific analyses. Gierczak T. 160. Mr. Gierczak referred during his testimony to a laboratory notebook that is used at Eco Logic which summarizes various steps performed on samples at the laboratory beginning from the time samples are received. *Id.* at 161-62.

19. Mr. Gierczak cited three references for the method used by Eco Logic in performing the analyses of Plaintiffs' blood samples: Berse; Swackhammer; and EPA method 680. Peterson T. 193-94. At his deposition, Mr. Gierczak referred to the Berse paper as the method he followed in performing the analyses. *Id.* at 194.

20. After reviewing the laboratory documents and chromatograms, Mr. Peterson stated that Mr. Gierczak made several deviations from the technique described in the Berse paper. There were several deviations in terms of the clean-up process and the Berse paper was not followed much after the extraction process. *Id.*

21. Eco Logic produced two sets of printouts of data. Gas chromatography/mass spectrometry ("mass spectrometry") and gas chromotography/electron capture analysis ("electron capture analysis") are the two analytical techniques employed by Eco Logic. *Id.* at 187, 195.

22. Electron capture analysis is often used to analyze PCBs because the detector responds well to chlorinated substances but this method does not provide as much qualitative information as mass spectrometry which also responds well to PCBs. *Id.* at 196. The basic process for measuring a compound is quite different between mass spectrometry and election capture analysis. *Id.* at 196-97.

23. The purpose of quality assurance is that it basically validates the analysis performed. Quality assurance tells the analyst and other persons reviewing the data that it is reliable. *Id.* at 198. Mr. Peterson stated that quality assurance is "absolutely essential" for the type of analysis involved in this case. *Id.* Every analytical technique and every piece of data requires quality assurance in order to validate its accuracy. *Id.* at 198-99. "In the quality assurance procedures, you generate data, which tells you that what you're measuring is correct. The identity of those compounds and the levels which you have measured is correct." *Id.* at 199.

24. Mr. Gierczak identified an Eco Logic booklet entitled "Quality Assurance, Quality Control Manual for the Analysis of Trace Organic Compounds" which he admitted was "put together . . . for the subpoena" after the analyses on Plaintiffs' samples were performed. Gierczak T. 232. Mr. Gierczak stated that prior to the subpoena, this booklet existed in maybe two or three pieces. *Id.*

25. The use of lab blanks is one example of a quality assurance procedure. A lab blank is used in order to determine what the background level is for the analyte that you are measuring. Peterson T. 199. Eco Logic used blank water in this case. Eco Logic carried the water through the analytical process, analyzed it with the same instrumentation as Plaintiffs' samples and looked for the presence of PCBs in that blank sample. *Id.* Dr. Peterson testfied that this is a standard laboratory technique. *Id.* Eco Logic found PCBs in the laboratory blank which Dr. Peterson stated that this in itself is not unusual. He stated that the PCBs could have come from a variety of sources, for example, "[t]he equipment, the glassware, the water itself, it's difficult to determine, but, it's introduced by the laboratory, in some manner." *Id.* at 200. Eco Logic ran only one laboratory blank in this case. *Id.* at 200-01, 217.

26. The level of PCBs in the laboratory blank was 3 parts per billion. *Id.* at 218. Eco Logic's "Qality Control Manual" states that "[b]lanks are used to determine if there's a significant contribution of analyte to the sample extract from sources other than the sample" and that "[a] significant result may suggest contamination from the laboratory, in which case, the cause must be located and corrected." Gierczak T. 235-36. Mr. Gierczak stated that the PCBs in the blank could have been introduced into the water but these PCBs did not come from Plaintiffs' samples. *Id.* at 240. He also admitted that he testified at his deposition that "there [was] no evidence" of "background laboratory contamination." *Id.* at 235.

27. Mr. Gierczak testified that it is misleading to compare only total PCB concentrations in the samples with the levels of PCBs found in the laboratory blank. He stated that "I think you need to look at the individual congeners to show really what's going on behind the scenes." *Id.* at 179. However, Mr. Gierczak admitted that, in regard to the specific congeners employed by Dr. Nisbet in performing his back-calculations, the levels found

in the laboratory blank exceeded the values reported for at least one Plaintiff. *Id.* at 239. The laboratory blank revealed 1.3 parts per billion of PCBs compared to levels found in Plaintiff Amber Burrell of 1.2 parts per billion. *Id.* This level of background contamination is "almost indistinguishable" from the levels reported in Plaintiff Amber Burrell's blood sample. Peterson T. 217-18.

28. Mr. Gierczak acknowledged that Eco Logic did not run the "vacutainer blanks," which were described in his initial report which was faxed to Dr. Nisbet, and that only one of the three matrix spike duplicates identified in this report had been analyzed. Gierczak T. 210-11.

29. A surrogate spike involves adding a compound to the sample which is very close in its characteristics to the analytes that are to be measured. The surrogate spike is used as a means of determining how the analytical process measured the analytes of that particular sample. Peterson T. 202. A matrix spike involves taking blank blood and spiking it with all the analytes that are to be measured. This spike sample is analyzed and the results are compared to the actual amount of the analyte that was added to the blank blood sample. *Id.* at 203.

30. A recovery rate compares the difference between the amount of the analytes actually measured in your spiked sample and the amount actually added to that sample. *Id.* at 204. Dr. Peterson stated that the matrix spike recovery rate should equal the surrogate recovery rate. *Id.* The recovery rates of the spikes analyzed by Eco Logic were not the same. "The surrogates were recovered at about 50 percent, while the matrix spikes were recovered at 100 percent." *Id.* Dr. Peterson testified that this inconsistency indicates a problem in Eco Logic's quantitation. *Id.* at 204-05.

31. In addition, Dr. Peterson stated that the levels at which the surrogate spikes and the matrix spikes were measured were extremely too high. These levels were

much higher than the levels Eco Logic ultimately generated as the level of PCBs in Plaintiffs' blood samples. *Id.* at 205.

32. Dr. Peterson testified that there was no quality assurance data provided for the results obtained by mass spectrometry. *Id.* at 215. There were no matrix or surrogate spike samples analyzed by mass spectrometry. *Id.* Dr. Peterson stated that "[i]n absence of [this] recovery data, I don't think you can be confident in the results here." *Id.* at 216.

33. A calibration range is the range of concentrations of your standards with which you calibrate your instruments. *Id.* at 206. Standard solutions are prepared, injected into the instrument and analyzed to assess the response of the instrument for that level of concentration. *Id.* at 240. Response factors are established for the various analytes on the instrument for that particular day. *Id.* at 206. The purpose of calibrating instruments is to ensure that quantitation is done accurately. Dr. Peterson stated that a range is established according to what the range of the actual analytes to be measured is anticipated to be. *Id.* at 207.

34. The results of the analyses performed on Plaintiffs' samples by Eco Logic did not fall within the calibration range which was set up for the testing by the electron capture analysis. *Id.* "[A]ll of the calibration standards were higher than any of the analyte concentrations which were measured." *Id.* The calibration range was at times higher by a factor of two and at other times higher by a factor of 100. *Id.* at 208. Mr. Gierczak testified that some of the PCB congeners came very close to falling within the calibration range. Gierczak T. 219. "Well, they fall in the estimation of Eco Logic, well within the calibration table, the linear range of the calibration table." *Id.* at 186. However, Mr. Gierczak admitted that "not one" of the PCB congeners that he analyzed

actually fell within the five point calibration range. *Id.* at 219-20.

35. A calibration range was also set up for the mass spectrometry data. Dr. Peterson testified that "[t]he concentrations measured in the real samples fell below the calibration range in the mass spectrometer." Peterson T. 208.

36. Dr. Peterson testified regarding the importance of having a calibration range which encompasses the levels measured in the actual samples especially at the low levels measured in this case. "[I]t will affect your accuracy because you're not really sure how the instrument behaves at the very low levels, because you have no standards which have been run at that level." *Id.* at 209. Dr. Peterson stated that the effect of having sample results which fall outside the calibration range is that it makes Eco Logic's results "less accurate." *Id.*

37. In electron capture analysis, a laboratory typically uses two columns. The first column is the analytical column ("DB5 column") which is where the quantitation takes place. *Id.* at 210. The second column is the confirmation column ("DB17 column") which is the column that is basically run to confirm the identities of the individual congeners analyzed. *Id.* Dr. Peterson testified that it is essential to compare peak-by-peak the peaks on the DB5 column to the peaks on the DB17 column. *Id.* at 211. Dr. Peterson stated that a confirmation column is required in this type of analysis because if such a column is not used there is a great possibility of "misidentifying the individual congeners, not only as PCBs, but also misidentifying them as some other compounds." *Id.* Dr Peterson testified that it is extremely possible that compounds other than PCBs are reported in the Eco Logic results. *Id.* at 212. Moreover, there is a high likelihood that some of the congeners are misidentified with respect to what congeners they are or with respect to other chemicals that may have been in the blood. *Id.* at

214. Dr. Peterson testified that he had little confidence that the identifications were correct due to the lack of confirmation. *Id.* at 219.

38. Mr. Gierczak admitted that the purposes of the DB17 column is to prevent the potential misidentification of another compound. Gierczak T. 217. In addition, in his affidavit which was submitted with his testimony at page three, Mr. Gierczak stated that the DB17 column is "absolutely critical to the overall analysis." Eco Logic's "Quality Control Manual" states that "the presence of an analyte is confirmed only when identified on both columns." *Id.* at 233. However, Mr. Gierczak was unable to state whether any of the 15 PCB congeners listed in his affidavit had been identified on the DB17 column or on the mass spectrometer. *Id.* at 215-16.

39. There are certain congeners that appeared in both the mass spectrometry results and the electron capture analysis results. *Id.* at 216. For example, PCB 118 was run by both of these methods. However, the results on PCB 118 differed between these two methods by a factor of two, almost three. *Id.* at 216-17. Dr. Peterson stated that this inconsistency points to a problem in the accuracy of the analyses. *Id.* at 217.

40. When Dr. Nisbet was shown Eco Logic's results from the DB17 column at the *in limine* hearing, he was unable to locate congeners 180, 118, 205 and 206 on the DB17 column even though he relied upon the presence of these congeners in performing his back-calculations. Nisbet T. 128-30. These congeners are not found on Eco Logic's DB17 column results. *Id.* at 127-30. Mr. Gierczak testified that he knew of no other print-out from the DB17 column. Gierczak T. 229-30. Dr. Nisbet stated that he did not use Eco Logic's confirmation because he had not seen it at the time that he did his back-calculations. Nisbet T. 130. Dr. Nisbet testified that he confirmed the presence of specific congeners only from the chromatograms. *Id.* at 129. However, he then agreed

that one could not confirm a peak on a DB17 column with a peak on a DB5 column by merely looking at the chromatograms. *Id.* at 131.

41. Dr. Peterson testified that he considered the data produced by Eco Logic on the six Plaintiffs to be unreliable. Peterson T. 220. He also stated that he would not feel comfortable allowing data such as that produced by Eco Logic to be released from Pacific Toxicology Laboratories. *Id.* at 219-20.

CONCLUSIONS OF LAW

1. In cases involving proffers of scientific evidence, the Third Circuit stated that "[i]t would appear that the most efficient procedure that the district court can use in making the reliability determination is an *in limine* hearing." *United States v. Downing,* 753 F.2d 1224, 1241 (3d Cir. 1985). The court went on to state that "[i]n the course of the *in limine* proceeding, the trial court may consider, *inter alia,* offers of proof, affidavits, stipulations, or learned treatises . . . in addition to testimonial or other documentary evidence (and, of course, legal argument)." *Id.*

2. This Court has before it a developed record and specific findings regarding reliability issues. *In re Paoli R.R. Yard PCB Litigation,* 916 F.2d 829, 858 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight,* 111 S. Ct. 1524 (1991). This Court has made a factual inquiry and finding as to what data experts in the field find reliable. *In re Japanese Electronic Products Antitrust Litigation,* 723 F.2d 238, 277 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574 (1986).

3. The Federal Rules of Evidence embody a strong preference for admitting evidence that has some potential of assisting the jury. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.,* 911 F.2d 941, 956 (3d Cir. 1990).

4. The hearings held by this Court relating to Defendants' Motion *In Limine* to Exclude Results of Analyses Performed by Eco Logic have produced a sufficient record to evaluate this evidence under Federal Rules of Evidence 702 and 703.

I. EXCLUSION BASED UPON RULE 702

5. Rule 702 of the Federal Rules of Evidence ("Rule 702") provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

6. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert and is helpful to the trier of fact." *DeLuca,* 911 F.2d at 954 (citations omitted).

7. Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based upon unreliable methodology is unhelpful and thus excludable. *DeLuca,* 911 F.2d at 954.

8. The focus of the Rule 702 inquiry is on the reliabiliy of the methodology employed by the expert in reaching his or her conclusions. *Paoli,* 916 F.2d at 856-57; *Downing,* 753 F.2d at 1238.

9. If a reliable methodology was "so altered as to skew the methodology itself, *Downing* would be the appropriate vehicle for evaluation" but not if the challenged procedure was an application of an accepted methodology. *Paoli,* 916 F.2d at 858 (citing *DeLuca,* 911 F.2d at 955 n.15).

10. *Downing* requires a district court to conduct a preliminary inquiry focusing on:

(1) the soundness and reliability of the process or technique used in generating the evidence,

(2) the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury, and

(3) the proffered connection between the scientific research or test result to be presented, and particular disputed factual issues in the case.

753 F.2d at 1237.

11. The reliability inquiry is flexible. The court may examine a variety of factors in addition to scientific evidence in assessing reliability of a particular technique or methodology. *Downing,* 753 F.2d at 1238. For example, the court may examine the expert's technique in relation to more established modes of scientific analysis and the existence of specialized literature dealing with the expert's technique or methodology. Other factors include: the non-judicial uses to which the scientific technique are put; the qualifications of the expert witness; and the frequency with which the methodology or technique leads to erroneous results. *Id.* at 1239.

12. After assessing the reliability of an expert's methodology, the court must determine whether admitting the evidence would overwhelm, confuse or mislead the jury. *See DeLuca,* 911 F.2d at 957.

13. "This inquiry focuses on the extent to which probative scientific evidence is capable of being properly utilized by the jury . . . ." *Id.*

14. The touchstone of Rule 702 is the "helpfulness of the expert testimony, *i.e.,* whether it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Downing,* 753 F.2d at 1235 (quoting Fed. R. Evid. 702).

15. Helpfulness turns on whether the expert's methodology is sufficiently reliable so that it will aid the jury in reaching accurate conclusions. *DeLuca,* 911 F.2d at 956 (citation omitted).

16. Where the record and factual findings demonstrate that the expert used an unreliable scientific mode of analysis and thus obtained "inaccurate results" from this analysis, the court must exclude the proffered testimony pursuant to Federal Rule of Evidence 702. *See Paoli,* 916 F.2d at 857.

17. Defendants argue that Mr. Gierczak is not qualified under Rule 702 to testify as an expert in analytical chemistry or congener specific analysis.

18. Rule 702 should be interpreted liberally. *Paoli,* 916 F.2d at 855. However, an expert must demonstrate special competence to present expert testimony. *Id.* at 862 (citation omitted). Based upon all the evidence presented, I find that Mr. Gierczak lacks the "knowledge, skill, experience, training or education" necessary to qualify him as an expert in either analytical chemistry or analyzing human blood samples by congener specific analysis. In terms of his experience and skill, this is the first report that Mr. Gierczak has issued concerning the congener specific analysis of human blood for PCBs. Findings of Fact ("FF") ¶ 13. Relating to his training and education, Mr. Gierczak's undergraduate courses in analytical chemistry do not qualify him as an expert in this field. *Id.* Plaintiffs have failed to establish Mr. Gierczak's "special competence" that is required under Rule 702 in order to testify as an expert.

19. Defendants also argue that Eco Logic altered an accepted methodology to such a point as to render Eco Logic's methodology unreliable under Rule 702.

20. Dr. Peterson testified that a confirmation column is required in this type of analysis because if such a column is not used there is a great possibility of mis-

identifying the individual congeners. FF ¶ 37. He stated that it is extremely possible that compounds other than PCBs are reported in the Eco Logic results. Dr. Peterson testified that he had little confidence that the identifications were correct due to the lack of confirmation. *Id.* Mr. Gierczak admitted that the purposes of the DB17 column is to prevent the potential misidentification of another compound. FF ¶ 38. In addition, he stated that the DB17 column is "absolutely critical to the overall analysis." *Id.* Mr. Gierczak was unable to state whether any of the 15 PCB congeners listed in his affidavit had been identified on the DB17 column or on the mass spectrometer. *Id.*

21. Dr. Peterson testified that Eco Logic failed to perform steps that are essential to the type of analyses it employed which included: failure to provide a written laboratory protocol describing the congener specific analyses performed; failure to provide adequate quality assurance data; failure to perform proper analytical and quantitative methods; failure to establish a sufficient calibration range; and failure to confirm all identifications using data from the DB17 column. FF ¶¶ 16, 18-31, 33-38. The potential for erroneous or inaccurate results was shown by Dr. Peterson to be extremely likely. FF ¶¶ 30, 32, 33-37, 39.

22. I find that Dr. Peterson is well qualified under Rule 702 to evaluate analyses employed by Eco Logic. *See* FF ¶¶ 4-7.

23. I conclude that the analyses performed by Eco Logic will not aid the jury in reaching accurate conclusions under Rule 702. Furthermore, Eco Logic has altered an accepted methodology to such a point as to render its methodology unreliable under Rule 702 since Eco Logic failed to perform various steps which are significant and "absolutely essential" in the type of analyses employed. Eco Logic's unreliable methodology is unhelpful and thus excludable.

II. EXCLUSION BASED UPON RULE 703

24. Rule 703 of the Federal Rules of Evidence ("Rule 703") provides that:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

25. The proper inquiry is not what the court considers reliable, but what experts in the relevant discipline consider to be reliable. *Japanese Electronic,* 723 F.2d at 276 (citations omitted).

26. This Court has a "proper and reviewable foundation for making its admissibility findings," *Paoli,* 916 F.2d at 853, and has conducted the requisite factual inquiry under *Japanese Electronic* to determine what type of facts or data experts in the field of exposure assessment find reliable. 723 F.2d at 276.

27. "If a study's method of data collection is faulty, it may well be that no expert would rely upon the data generated as a basis for drawing any inference about the studied subject." *DeLuca,* 911 F.2d at 955 n.14.

28. I find that Dr. Peterson is well qualified to testify as to what data experts in the field of analytical chemistry rely upon to reach their conclusions. *See* FF ¶¶ 4-7.

29. Dr. Peterson stated that the matrix spike recovery rate should equal the surrogate recovery rate. The recovery rates of the spikes analyzed by Eco Logic were not the same. Dr. Peterson testified that this inconsistency indicates a problem in Eco Logic's quantitation. FF ¶ 30.

30. Quality assurance tells the analyst and other persons reviewing the data that it is reliable. FF ¶ 23. Dr. Peterson testified that there was no quality assurance data provided for the results obtained by mass spectrometry. There were no matrix or surrogate spike samples analyzed by mass spectrometry. Dr. Peterson stated that "[i]n absence of [this] recovery data, I don't think you can be confident in the results here." FF ¶ 32.

31. The purpose of calibrating instruments is to ensure that quantitation is done accurately. FF ¶ 33. The results of the analyses performed on Plaintiffs' samples by Eco Logic did not fall within the calibration range which was set up for the testing by the electron capture analysis. "[A]ll of the calibration standards were higher than any of the analyte concentrations which were measured." The calibration range was at times higher by a factor of two and at other times higher by a factor of 100. FF ¶ 34. Dr. Peterson also stated that the concentrations measured in Plaintiffs' samples fell below the calibration range in the mass spectrometer. FF ¶ 35. Dr. Peterson testified regarding the importance of having a calibration range which encompasses the levels measured in the actual samples, especially at the low levels measured in this case. "[I]t will affect your accuracy because you're not really sure how the instrument behaves at the very low levels, because you have no standards which have been run at that level." FF ¶ 36. Dr. Peterson stated that the effect of having sample results which fall outside the calibration range is that it makes Eco Logic's results "less accurate." *Id.*

32. In electron capture analysis, Dr. Peterson testified that it is essential to compare peak-by-peak the peaks on the DB5 column to the peaks on the DB17 column. He stated that a confirmation column is required in this type of analysis because if such a column is not used there is a great possibility of "misidentifying the individual congeners, not only as PCBs, but also misidentifying them

as some other compounds." Dr. Peterson testified that it is extremely possible that compounds other than PCBs are reported in the Eco Logic results and that he had little confidence that the identifications were correct due to the lack of confirmation. FF ¶ 37. Mr. Gierczak admitted that the purposes of the DB17 column is to prevent the potential misidentification of another compound. In addition, he stated that the DB17 column is critical to the overall analysis. Eco Logic's "Quality Control Manual" states that "the presence of an analyte is confirmed only when identified on both columns." Mr. Gierczak was unable to state whether any of the 15 PCB congeners listed in his affidavit had been identified on the DB17 column or on the mass spectrometer. FF ¶ 38.

33. There are certain congeners that appeared in both Eco Logic's mass spectrometry results and Eco Logic's electron capture analysis results. PCB 118 was run by both of these methods. The results on PCB 118 differed between these two methods by a factor of two, almost three. Dr. Peterson stated that this inconsistency points to a problem in the accuracy of the analyses. FF ¶ 39.

34. Dr. Peterson considered the data produced by Eco Logic on the six Plaintiffs to be unreliable. He also stated that he would not feel comfortable allowing data such as that produced by Eco Logic to be released from Pacific Toxicology Laboratories. FF ¶ 41.

35. I conclude based upon the entire record before me that the results of the analyses performed by Eco Logic on Plaintiffs' blood samples are not data of the type reasonably relied upon by experts in the field of analytical chemistry as required under Rule 703. Thus, all testimony concerning these results must be excluded.

36. I have concluded in a separate memorandum to exclude the testimony of Dr. Nisbet under Rules 702 and 703.

For the foregoing reasons, I conclude that the analyses performed by Eco Logic are unreliable under Rule 702. In addition, Eco Logic's results of the analyses performed on Plaintiffs' blood samples are not data which is reasonably relied upon by experts in the field of analytical chemistry under Rule 703. Thus, all testimony concerning these results must be excluded. I shall enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Andre Williams v. *Septa, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Results of Analyses Performed by ELI Eco Logic Laboratories, Inc., all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
Sylvan Cohen, et al. v. *Septa, et al.*	No. 86-4037
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
James Lament v. *Septa, et al.*	No. 86-5886
Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight . *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

R.F. KELLY, J. October 21,1992

[As Amended February 1, 1993]

MEMORANDUM

MOTION IN LIMINE TO EXCLUDE REFERENCES TO DIOXIN, FURANS, TIN TETRAPHENYL, AND EPOXIDES

This is another of the many motions *in limine* filed by Defendants in the above captioned case. Defendants request that this Court exclude all testimony, evidence, or statements to the jury by Plaintiffs, their counsel or their witnesses concerning polychlorinated dibenzo-p-dioxins ("dioxin"), polychlorinated dibenzofurans ("furans"), tin tetraphenyl, and epoxide dicyclodiepoxy carboxylate ("EDDC").

All of the Plaintiffs or their decedents are or were residents of the neighborhood adjacent to the Paoli Railyard (the "Yard"). They allege injury and damage as a result of exposure to polychlorinated biphenyls ("PCBs") which were an ingredient of fire resistant fluid used in electrical transformers attached to the underside of the railroad cars which were serviced and maintained in the Yard.

These Plaintiffs allege that they were exposed to PCBs through dermal contact with soil contaminated by PCBs from the Yard, eating vegetables grown in gardens with soil contaminated by PCBs, and inhalation of windblown PCB-contaminated dust. None of these Plaintiffs claim exposure by virtue of having been employed in the Yard.

Plaintiffs intend to assert that they were also exposed to dioxin and furans because small amounts of those chemicals were detected in soil samples taken from inside the Yard. Plaintiffs also intend to assert that they were exposed to other chemical ingredients of PCB-containing dielectric fluid including tin tetraphenyl and EDDC [1] because small amounts of tin tetraphenyl and EDDC were included as intentional ingredients in PCB-

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[1] EDDC is one of a large class of chemicals known collectively as the "epoxides."

containing dielectric fluid. From the testimony taken on this and other motions *in limine*, deposition testimony, exhibits and record papers, this Court makes the following:

FINDINGS OF FACT

1. Tin tetraphenyl was an intended ingredient of the dielectric fluid used in transformers manufactured by General Electric Company from approximately 1944 to 1963. Its purpose was to serve as an hydrochloric acid scavenger. Tin tetraphenyl comprised only 0.125% of the total finished product composition. Rouse Dep. 194 and Exhibits 1 and 4 attached thereto.[2]

2. EDDC was an intended ingredient of the dielectric fluid used in transformers manufactured by General Electric Company from approximately 1963 to 1977. Its purpose was to serve as an hydrochloric acid scavenger. EDDC comprised only 0.125% of the total finished product composition. Rouse Dep. 194 and Exhibits 1 and 4 attached thereto.

3. There is no evidence in the record in this case that any soil samples taken inside the Yard were ever analyzed for the presence of tin tetraphenyl or EDDC. Indeed, the Plaintiffs have offered no evidence whatsoever that either tin tetraphenyl or EDDC was ever present at the Yard beyond the speculative inference that since they were an original ingredient of dielectric fluid then they might be present in the Yard.

4. There is no evidence in the record in that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of tin tetraphenyl or EDDC.[3]

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[2] "Rouse Dep." refers to the deposition testimony of Thomas Owen Rouse, Ph.D., taken on August 1, 1990 and July 22, 1991.

[3] Analyses of soil samples from the yards of several of these Plaintiffs were procured by Plaintiffs' attorneys, but they were

5. There is no evidence in the record in this case that any of the blood or adipose tissue samples taken from these Plaintiffs was ever analyzed for the presence of tin tetraphenyl or EDDC.[4]

6. There is no evidence in the record that either of the Plaintiffs' "exposure experts," Dr. Ian Nisbet and Dr. Melvyn Kopstein, performed an exposure analysis of any kind with respect to tin tetraphenyl or EDDC or attempted to quantify the extent to which any Plaintiff might have been exposed to tin tetraphenyl or EDDC. Indeed, there is not even a reference to these chemicals in either their extensive deposition testimony or their *in limine* testimony.

7. Plaintiffs' response to this motion completely fails to address Defendants' position with respect to tin tetraphenyl and is therefore deemed to admit and concede its correctness.

8. Although Plaintiffs' response to this motion asserts that the Defendants Monsanto, General Electric and Westinghouse "continued to use a methylated epoxide in transformer fluids, epoxide 201, well after they learned it could cause cancer," Plaintiffs' Response 57,[5] it does

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not analyzed for the presence of tin tetraphenyl or EDDC. *See* BCM Eastern, Inc. documents attached to Defendants' Reply Memorandum of Law in Support of Defendants' Motion *In Limine* to Exclude the Testimony of Plaintiffs' Expert, Melvyn Kopstein, Ph.D., dated and served on July 13, 1992.

[4] Plaintiffs' attorneys procured PCB analyses of blood and adipose tissue samples from many of these Plaintiffs, but did not include an analysis for the presence of tin tetraphenyl of EDDC. *See generally* Deposition and *in limine* testimony of Plaintiffs' experts, Drs. Sherman, Nisbet, DiGregorio, and Plaintiffs' Memorandum In Opposition To Defendants' Motions *In Limine* And In Support Of Plaintiffs' Motion To Strike, Dated July 8, 1992.

[5] "Plaintiffs' Response" refers to Plaintiffs' Memorandum In Opposition To Defendants' Motions *In Limine* And In Support Of Plaintiffs' Motion To Strike, dated July 8, 1992.

not address the Defendants' position that there is no evidence to establish that any of these Plaintiffs were ever exposed to EDDC or any other epoxide. It is therefore deemed that Plaintiffs have admitted and concede its correctness.

9. Unlike tin tetraphenyl and EDDC, there is evidence that dioxin and furans were measured in the Yard in very minute quantities. Approximately eighteen soil samples taken from inside the Yard were analyzed for dioxin and furans and their arithmetic average resulted in a dioxin toxicity equivalent of 0.603 parts per billion ("ppb"). This level is below the "CDC level of concern" of 1.0 ppb utilized by the Environmental Protection Agency in "The National Dioxin Study, EPA-440/4-87/003 (1987). *See* "Final Remedial Investigation and Risk Assessment," Paoli Railroad Yard, dated October 29, 1990.

10. There is no evidence in this case that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of dioxin or furans.[6]

11. There is no evidence in the record that any of the blood or adipose tissue samples taken from these Plaintiffs were ever analyzed for the presence of dioxin or furans. Plaintiffs' attorneys procured PCB analyses of blood and adipose tissue samples from many of these Plaintiffs, but did not include an analysis for the presence of dioxin or furans. *See generally* Testimony of Plaintiffs' experts, Drs. Sherman, Nisbet and Schecter. In addition, Plaintiffs' expert, Dr. Ian Nisbet, requested blood samples from six of these Plaintiffs and procured Eco Logic Laboratories, Inc. to perform congener specific

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[6] Analyses of soil samples from the yards of several of these Plaintiffs were procured by the Plaintiffs' attorneys, but they were not analyzed for the presence of dioxin or furans. *See* footnote, 2, *supra*.

analyses for PCBs but did not have the samples analyzed for dioxin, furans, tin tetraphenyl or EDDC. Likewise, Plaintiffs' expert, Dr. Janette Sherman, procured blood samples from ten of these Plaintiffs for the purpose of immunological testing by Antibody Assay Laboratories but never requested blood analyses for PCBs, dioxin, furans, tin tetraphenyl, or EDDC. Finally, this Court notes that these cases have been pending for at least 5 years or more and the Plaintiffs have had ample opportunity to have their blood or adipose tissue tested for the presence of dioxin, furans, tin tetraphenyl and EDDC (and at a time less remote from the period of alleged exposure), but not one has done so.

12. This Court heard *in limine* testimony on July 31, 1992, of Robert C. James, Ph.D., an Associate Professor at the Center for Environmental and Human Toxicology at the University of Florida and an author of approximately 50 publications in the field of toxicology, who was qualified as an expert in toxicology and pharmacology. James T. 74-81.[7] Dr. James testified that, in toxicology, the term "exposure" refers to "the eligilibity to have contact with the chemical," while the term "dose" refers to "the amount of chemical that's actually absorbed into the body." James T. 83. He explained that even when a person has been exposed to a chemical, it does not necessarily follow that the person has received a dose. He said: "There are a number of papers that have discussed and indicated that exposure is not a good measure of dose, and in fact, there is a recent paper by the Center for Disease Control that discussed this concept and problem in general, that we're finding particularly with environmental contamination that exposure extrapolation methods do not agree with actual measures of dose. And that unless dose extrapolation methods are then calibrated with some measure of dose, that they can

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[7] "James T." refers to the July 31, 1992, transcript of the *in limine* hearing in this action.

be misleading." James T. 83-84. Finally, Dr. James explained that the "[d]ose response relationship is the basic principle that toxicologists use to determine the safety or relative risk of a particular dose that a person has received. So it is a mathematical or graphical understanding of the doses over which the chemical produces no effect, and the doses that it produces whatever adverse effect that we're concerned with." James T. 85.

13. While Dr. Melvyn Kopstein did speculate how residential soils might have become contaminated with furans and dioxin, and how Plaintiffs might have been exposed to these chemicals, he admitted that he was unable to quantify any levels of residential contamination and does not believe that anyone could do a competent exposure analysis in this case. Kopstein T. 49-50, 58-61.[8] Furthermore, in his deposition, Dr. Kopstein conceded that there was insufficient data on residential contamination by dioxin and furans to perform a scientific computation of exposure: "there is *absolutely no data* that I've been able to find having to do with dioxin or furans off the site, and only sparse information about these chemicals on the site. So if you *don't really know what's present for sure,* and in what concentrations, then it's not possible to perform this type of computation." Kopstein Dep. 102 (emphasis added).[9]

14. There is no competent evidence in this case that these Plaintiffs were ever exposed to dioxin or furans because there is no evidence that these substances were present in the Yard in any significant amount or that they "migrated" off of the Yard and were present in the adjacent neighborhood or in the soil to which these Plaintiffs were exposed.

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[8] "Kopstein T." refers to the July 31, 1992, transcript of the *in limine* hearing in this action.

[9] "Kopstein Dep." refers to the deposition testimony of Melvyn Kopstein, Ph.D., taken on May 11, 1992.

15. There is no evidence in the record whatsoever that these Plaintiffs received any dose of dioxin or furans; that is, there is no evidence that these Plaintiffs had an up-take of dioxin or furans into their bodies.

16. The Court will judicially note that dioxin has received a great deal of adverse notoriety in the public press and has been described in the press as "the most toxic chemical known to man."

CONCLUSIONS OF LAW

1. The thrust of Defendants' motion *in limine* is that there is no evidence that the Plaintiffs in this case have received any internal dose whatsoever of the chemicals or have been externally exposed at all to dioxins, furans, tin tetraphenyl or epoxides. Plaintiffs argue in their response to this motion that: Defendants' contractor, GTI, failed to investigate for any toxic substance other than PCBs; dioxins and furans have toxic effects; and "certain heat producing operations" *i.e.*, burning, welding, etc., could have converted PCBs into other toxins such as dioxins and furans.

These responses totally ignore Defendants' argument that the soil samples from inside the Yard and from the surrounding properties were never tested for tin tetraphenyl or EDDC. Approximately eighteen soil samples taken from inside the Yard were analyzed for dioxin and furans and their arithmetic average resulted in a dioxin toxicity equivalent of 0.603 parts per billion in ("ppb"). This level is below the "CDC level of concern" of 1.0 ppb utilized by the Environmental Protection Agency in "The National Dioxin Study, EPA-440/4-87/003(1987). There is no evidence in this case that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of dioxin or furans. There is no evidence in this case that any of

the blood samples or adipose tissue taken from the Plaintiffs were ever analyzed for the presence of tin tetraphenyl, EDDC, dioxins or furans.

The issue then is not whether these categories of chemicals are harmful, the issue is whether there is any evidence in this case to indicate that they were present at all or present in quantities that could be deemed harmful. Plaintiffs response does not address that issue.

2. Rule 402 of the Federal Rules of Evidence ("Rule 402") provides that irrelevant evidence is inadmissible. The party offering evidence has the burden of establishing its admissibility. *Compagnie des Bauxites de Guinee v. Insurance Co. of North America,* 551 F. Supp. 12139 (D.C. Pa. 1982) (citing *Eastern Associated Coal v. Aetna Casualty & Surety Co.,* 632 F.2d 1068 (3d Cir. 1980)).

3. There is no evidence in the record that tin tetraphenyl or EDDC were ever present in the Yard or that these Plaintiffs were ever exposed to or received a dose of either of these substances.

4. There is no competent evidence in the record that these Plaintiffs were ever exposed to dioxin or furans because there is no evidence that these substances were present in the Yard in any significant amount or that they "migrated" off of the Yard and were present in the adjacent neighborhood or in the soil to which these Plaintiffs were exposed.

5. Further, there is no evidence in the record that these Plaintiffs received any dose of dioxin or furans; that is, there is no evidence that these Plaintiffs had an up-take of dioxin or furans into their bodies.

6. Therefore, evidence of the presence of dioxin or furans in very minute quantities in the Yard or the alleged adverse health effects associated with exposure to these substances would be irrelevant to the issues to be tried in Phase I of this trial.

7. Similarly, evidence of the presence of tin tetraphenyl or EDDC in the dielectric fluid as originally manufactured or any alleged adverse health effects assocated with exposure to these substances would be irrelevant to the issues to be tried in Phase I of this trial.

8. Rule 403 of the Federal Rules of Evidence ("403") provides that even relevant evidence may be excluded "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." When there is a risk that testimony and evidence may confuse or prejudice the jury, a party may properly file a motion *in limine* requesting the court to limit the scope of testimony. *Owens v. Concrete Pipe & Products Co.*, 125 F.R.D. 113 (E.D. Pa. 1989). Even where there is some evidence that trace amounts of these chemicals existed at the Yard, the trial court should exclude such findings where the probative value is outweighed by the danger of undue prejudice, confusion and delay. *In re Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd.*, 505 F. Supp. 1125 (1980), an antitrust action, factual findings from an investigation made pursuant to federal agencies' authority were inadmissible because they would invite irrelevant evidence and would result in a waste of time.

9. To permit the Plaintiffs, their witnesses or their counsel to present evidence concerning dioxin, furans, tin tetraphenyl or EDDC without any evidence that these Plaintiffs have been exposed to those substances would be prejudicial to the Defendants because they would be required to defend against a substance to which the Plaintiffs cannot prove they were exposed; confuse and complicate the issues for trial by necessitating the presentation of additional evidence to the jury to counter the allegations of exposure and health effects of substances to which the Plaintiffs cannot prove they were exposed; confuse and mislead the jury by focusing their attention on substances

to which the Plaintiffs cannot prove they were exposed; result in undue delay and wasting of time consumed in the presentation of irrelevant evidence at trial; and prejudice the Defendants by permitting inflammatory evidence concerning substances such as dioxin as to which there is much public sensitivity and fear.

10. The anticipated evidence concerning dioxin, furans, tin tetraphenyl and EDDC, even if relevant, is of such marginal probative value that it is clearly outweighed by the dangers enumerated in Rule 403 and analyzed above. Furthermore, the lack of evidence of exposure, the marginal probative value, and the prejudicial nature of the evidence make it unlikely that a limiting instruction would be effective.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
Sylvan Cohen, et al. v. *Septa, et al.*	No. 86-4037
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
James Lament v. *Septa, et al.*	No. 86-5886
Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight, v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

ORDER

AND NOW, this 21st day of Oct. 1992, the Defendants' Motion to Exclude All Testimony, Evidence or Statements to the Jury by Plaintiffs, their Counsel or their

Witnesses concerning Dioxin, Furans, Tin Tetraphenyl, and Epoxides, including EDDC or any alleged adverse health effects associated with or attributed to exposure to those substances, is hereby GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
Sylvan Cohen, et al. v. *Septa, et al.*	No. 86-4037
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
James Lament v. *Septa, et al.*	No. 86-5886
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
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Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

MEMORANDUM

R.F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE REFERENCES TO YUSHO AND YUCHENG

This is a toxic tort case brought by individuals who maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") from having either worked in or lived adjacent to the Paoli Railyard in Paoli, Pennsylvania. This Court held hearings on July 28, 29, 30, 31 and August 3 and 7, 1992 eliciting testimony and argument on the numerous motions *in limine* and dispositive motions filed in this action.

Defendants filed this motion *in limine* to exclude from trial all references to Yusho and Yucheng. Defendants argue that all references to the incidents that occurred concerning Yusho and Yucheng must excluded under Rules 402 and 403 of the Federal Rules of Evidence. Upon consideration of Defendants' Motion *In Limine* to Exclude References to Yusho and Yucheng, all responses thereto, the hearing and deposition testimony presented to this Court, and all exhibits admitted into evidence at the hearing, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. In Japan in 1968, a large number of people ate rice oil used for food preparation which had been accidentally contaminated in the manufacturing process with a heat transfer fluid containing Japanese-manufactured PCBs. (Commonly referred to as "Yusho"). There were a number of reported adverse health effects attributed to the oral ingestion of this rice oil which included chloracne, pigmentation of the skin and nails, swelling and numbness of the limbs, jaundice, eye discharge, joint pain, head-

aches, fever and respiratory symptoms. *See generally* Kimbrough, "Human Health Effects of Polychlorinated Biphenyls (PCBs) and Polybrominated Biphenyls (PBBs)," *ment*, 1, 20 (J. Waid, ed. 1987).

2. Although early scientific reports linked these adverse health effects to PCBs, scientists later discovered that the rice oil also contained other, more toxic, chemicals, specifically polychlorinated dibenzofurans ("furans" or "PCDFs") and polychlorinated quarterphenyls ("PCQs"). *Id.*

3. In Taiwan in 1979, a similar accidental posioning occurred which involved approximately 2,000 persons who ate rice oil contaminated with Japanese-made PCBs which contained high levels of furans and PCQs. (Commonly referred to as "Yucheng"). These persons exhibited similar symptoms as those described by the Yusho victims. *Id.*

4. The scientific literature overwhelmingly concludes that the presence of furans in the rice oil proved to be the major etiologic agent in causing the adverse health effects observed in the persons exposed by oral ingestion in Yusho and Yucheng. "It has been concluded [that] PCDFs are the primary causal agent of Yusho as well as of the Taiwan incident [Yucheng]." Kashimoto and Miyata, "Differences Between Yusho and Other Kinds of Poisoning Involving Only PCBs," *PCBs and the Environment*, 1, 20 (J. Waid, ed. 1987).

5. Exposure to PCDFs furans and PCQs, as well as PCBs, make the Yusho and Yucheng incidents dubious for any scientific study of the effects of PCBs on humans. *See* W.R. Gaffey, "The Epidemiology of PCBs," *PCBs: Human and Environmental Hazards*, 279, 280 (1983).

6. According to the Agency for Toxic Substances and Disease Registry ("ATSDR"): "There appears to be general agreement that the PCDF contaminants, particularly the more potent isomers, contributed significantly to the

health effects observed in the Yusho and Yucheng patients." ATSDR, *Toxicological Profile for Selected PCBs*, § 4.1 at p. 44 (June, 1989).

7. As acknowledged throughout the medical and scientific literature by respected researchers, PCDFs/furans are the clear etiologic agent in Yusho and Yucheng. It is not valid to attribute any adverse health effects to PCB exposure based upon the Yusho and Yucheng data. *See id.*; Gaffey, "The Epidemiology of PCBs," *PCBs: Human and Environmental Hazards*, 279, 280.

8. At the *in limine* hearing, Defendants presented the testimony of Robert C. James, Ph.D. ("Dr. James"). July 31, 1992 Hearing Testimony of Dr. James ("James T."). Dr. James is an Associate Professor at the Center for Environmental and Human Toxicology at the University of Florida and an author of approximately 50 publications in the field of toxicology. Dr. James was offered by Defendants as an expert in the fields of Toxicology and Pharmacology. James T. 74-81.

9. Dr. James testified that Yusho refers to an incident in which cooking oil was heated under a vacuum to drive off odorants. The heat exchanger being used to heat the oil utilized a PCB-containing heat exchange fluid. The heat exchanger leaked fluids into the cooking oil which became contaminated. *Id.* at 85-86. Dr. James stated that a common pattern of clinical manifestations were observed in the Yusho victims. The primary manifestations were chloracne, a brown discoloration of the nails, swelling of the eyelids, cheesy discharge from the eyes, hyperemia of the eyes, and a general malaise. These manifestations appeared in the Yusho victims as early as 20 days and as late as 150 days. *Id.* at 86-87. Dr. James testified that the contamination in the Yucheng incidents occurred in much the same manner as in Yusho and the same clinical manifestations appeared. *Id.* at 86.

10. Dr. James stated that this pattern of manifestations had never been reported either in studies of persons

occupationally exposed to PCBs or in studies of non-occupationally exposed persons. *Id.* at 87. He stated that this is due to the fact that "Yusho and Yucheng were caused by polychlorinated dibenzofurans [furans]." *Id.*

11. Dr. James testified that the Yusho victims never had anywhere near the PCB levels that have been reported in capacitor workers. Moreover, he stated that after the Yusho victims' PCB levels returned to normal, their symptoms did not disappear while their furan levels remained elevated which easily explained all of the symptoms. *Id.* at 88. Dr. James testified that the Yusho and Yucheng incidents are not helpful in predicting human health effects from exposure to PCBs. *Id.* Yusho and Yucheng involved a different chemical. *Id.*

12. Dioxin and furans were measured in the Paoli Railyard (the "Yard") in very minute quantities. Approximately 18 soil samples taken from inside the Yard were analyzed for dioxin and furans. The arithmetic average from these samples resulted in a dioxin toxicity equivalent of 0.603 parts per billion ("ppb"). This level is below the Center for Disease Control ("CDC") level of concern which is 1.0 ppb. This CDC level is utilized by the Environmental Protection Agency in "The National Dioxin Study, EPA-440/4-87/003 (1987). *See* "Final Remedial Investigation and Risk Assessment," Paoli Railroad Yard, dated October 29, 1990.

13. There is no evidence in the record that any of the soil samples taken from the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of furans.

14. There is no evidence in the record that any of the blood or adipose tissue samples taken from Plaintiffs were ever analyzed for the presence of furans. Plaintiffs' attorneys procured PCB analyses of many of the Plaintiffs' blood and adipose tissue samples but there were no analyses performed for the presence of furans. *See* Depo-

sition and *In Limine* Testimony of Drs. Sherman, Nisbet and Schecter.

15. These cases have been pending for at least five years. Plaintiffs have had ample opportunity to have their blood or adipose tissue samples tested for the presence of furans. Moreover, Plaintiffs have had ample opportunity to have soil samples from their yards analyzed for the presence of furans.

16. Dr. James testified that, in toxicology, the term "exposure" refers to "the eligibility to have contact with the chemical," while the term "dose" refers to "the amount of chemical that's actually absorbed into the body." James T. 83. He explained that even when a person has been exposed to a chemical, it does not necessarily follow that the person has received a dose. Dr. James stated that:

> There are a number of papers that have discussed and indicated that exposure is not a good measure of dose, and in fact, there is a recent paper by the Center for Disease Control that discussed this concept and problem in general, that we're finding particularly with environmental contamination that exposure extrapolation methods do not agree with actual measures of dose. And that unless dose extrapolation methods are then calibrated with some measure of dose, they can be misleading or inaccurate.

Id. at 84. Dr. James explained that "[d]ose response relationship is the basic principle that toxicologists use to determine the safety or relative risk of a particular dose that a person has received. So it is a mathematical or graphical understanding of the doses over which the chemical produces no [e]ffect, and the doses that it produces whatever adverse effect that we're concerned with." *Id.* at 85.

17. While Melvyn Kopstein, Ph.D. ("Dr. Kopstein") did speculate how residential soils might have become contaminated with dioxin and furans, and how Plaintiffs might have been exposed to these chemicals, he admitted that he was unable to quantify any levels of residential contamination and does not believe that anyone could do a competent exposure analysis in this case. July 31, 1992 Hearing Testimony of Dr. Kopstein at 49-50, 58-61 ("Kopstein T."). Furthermore, at his deposition, Dr. Kopstein conceded that there was insufficient data on residential contamination by dioxin and furans to perform a scientific computation of exposure: "there is absolutely no data that I've been able to find having to do with dioxin or furans off the site, and only sparse information about these chemicals on the site. So if you don't really know what's present for sure, and in what concentrations, then it's not possible to perform this type of computation." May 11, 1992 Deposition of Dr. Kopstein at 102 ("Kopstein Dep.") (emphasis added).

18. There is no competent evidence in this case that these Plaintiffs were ever exposed to furans. There is no evidence that these substances were present in the Yard in any significant amount or that they "migrated" off of the Yard and were present in the adjacent neighborhood or in the soil to which these Plaintiffs were exposed.

19. There is no evidence in the record whatsoever that these Plaintiffs received any dose of furans; that is, there is no evidence that these Plaintiffs had an up-take of furans into their bodies.

20. There is no evidence in the record that any of these Plaintiffs have ever been diagnosed as suffering from chloracne. The only testimony presented by Plaintiffs on this issue was that of Janette D. Sherman, M.D. ("Dr. Sherman") who diagnosed one Plaintiff as having contracted chloracne from exposure to PCBs. In a separate memorandum, I have concluded that Dr. Sherman was plainly not qualified to diagnose chloracne in any of

the Plaintiffs in this case. *See* Memorandum of this Court concerning Dr. Sherman, Findings of Fact 14-15, 37-39, 50. This Court granted Defendants' Motion *In Limine* to Exclude Opinion Testimony of Dr. Sherman under Rules 702, 703 and 403 of the Federal Rules of Evidence.

CONCLUSIONS OF LAW

1. In cases involving proffers of scientific evidence, the Third Circuit stated that "[i]t would appear that the most efficient procedure that the district court can use in making the reliability determination is an *in limine* hearing." *United States v. Downing*, 753 F.2d 1224, 1241 (3d Cir. 1985). The court went on to state that "[i]n the course of the *in limine* proceeding, the trial court may consider, *inter alia*, offers of proof, affidavits, stipulations, or learned treatises . . . in addition to testimonial or other documentary evidence (and, of course, legal argument)." *Id.*

2. The hearings held by this Court relating to Defendants' Motion *In Limine* to Exclude References to Yusho and Yucheng have produced a sufficient record to evaluate this evidence under Federal Rules of Evidence 402 and 403.

3. Rule 402 of the Federal Rules of Evidence ("Rule 402") provides that irrelevant evidence is inadmissible. Fed. R. Evid. 402. The party offering the evidence has the burden of establishing its admissibility. *Compagnie des Bauxites de Guinee v. Insurance Co. of North America*, 551 F. Supp. 1239 (W.D. Pa. 1982) (citing *Eastern Associated Coal v. Aetna Casualty & Surety Co.*, 632 F.2d 1068 (3d Cir. 1980)).

4. Defendants' main argument in support of its motion to exclude is that there is no evidence that Plaintiffs have received any internal dose whatsoever of furans or have been externally exposed at all to furans. Plaintiffs' response to this motion discusses the failure of Defendants' contractors to investigate for any toxic substance other

than PCBs. Plaintiffs argue the toxic effects of dioxin and furans, and they argue that "certain heat producing operations" *i.e.*, burning, welding, etc., could have converted PCBs into other toxins such as furans.

5. Plaintiffs simply ignore Defendants' arguments. Approximately eighteen soil samples taken from inside the Yard were analyzed for dioxin and furans and their arithmetic average resulted in a dioxin toxicity equivalent of 0.603 parts per billion in ("ppb"). This level is below the "CDC level of concern" of 1.0 ppb utilized by the Environmental Protection Agency. There is no evidence in this case that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of furans. There is no evidence in this case that any of the blood samples or adipose tissue samples taken from the Plaintiffs were ever analyzed for the presence furans. Moreover, there is no evidence in the record whatsoever that these Plaintiffs received any dose of furans; that is, there is no evidence that these Plaintiffs had an up-take of furans into their bodies. Findings of Fact ("FF") ¶¶ 12-14, 18-19.

6. Dr. James testified that the Yusho and Yucheng incidents are not helpful in predicting human health effects from exposure to PCBs. Yusho and Yucheng involved a different chemical. FF ¶ 11.

7. I conclude that the facts and circumstances of Yusho and Yucheng are substantially and significantly different from the circumstances involved in this case and these Plaintiffs. These differences include the following:

> (1) The Yusho and Yucheng victims had very high body levels of furans, whereas these Plaintiffs have no measured levels of furans in their bodies;
>
> (2) The principle route of exposure in Yusho and Yucheng was through eating cooking oil which was contaminated with furans, whereas these Plaintiffs

alleged a principle route of exposure through contract with contaminated soil;

(3) The Yusho and Yucheng victims were exposed to Japanese-manufactured PCB-containing heat transfer fluid that was made by a different manufacturing process;

(4) The length of time from exposure to manifestation of clinical symptoms in Yusho and Yucheng was from 20 to 150 days, whereas these Plaintiffs do not manifest these pattern of symptoms in a temporal relation to exposure; and

(5) The leading sign or illness exhibited by the victims of Yusho and Yucheng was chloracne, whereas there is no evidence in the record that any of these Plaintiffs have been diagnosed as having chloracne.

FF ¶¶ 1-4, 9-11, 14, 16-18, 20.

8. Therefore, I conclude that evidence concerning health effects experienced by Yusho and Yucheng victims is irrelevant to this case under Rule 402 and must be excluded. I find that this evidence is irrelevant to Plaintiffs' claims of adverse health effects from exposure to PCBs through soil contamination.

9. Rule 403 of the Federal Rules of Evidence ("403") provides that even relevant evidence may be excluded "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

10. I find that to permit Plaintiffs to present evidence concerning the Yusho and Yucheng incidents or the health effects experienced by the victims of these incidents would be unfairly prejudicial to Defendants since Defendants would be required to defend against claims

of health effects resulting from exposure to furans and Plaintiffs have failed to provide any evidence that Plaintiffs were exposed to furans. Moreover, admission of this evidence will also confuse and mislead the jury by focusing their attention on circumstances and health effects caused by furans to which Plaintiffs cannot prove they were exposed. Furthermore, Defendants would be greatly prejudiced by this evidence since it concerns a widespread poisoning caused by a substance to which Plaintiffs cannot establish they were exposed.

11. I conclude that evidence concerning the Yusho and Yucheng incidents, even if relevant, is of such marginal probative value that it is clearly outweighed by the danger of unfair prejudice to Defendants and the danger of confusing or misleading the jury. I find that a limiting instruction would be ineffective in alleviating these dangers. Therefore, all evidence concerning the Yusho and Yucheng incidents must be excluded under Rule 403.

I shall enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

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ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude References to Yusho and Yucheng, all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-F

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

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MEMORANDUM

R.F. KELLY, J. October 21, 1992

[As Amended February 1, 1993]

DEFENDANTS' MOTION TO PRECLUDE TESTIMONY OF DRS. CALESNICK, BARSOTTI, ZAHALSKY, NICHOLSON AND JENKINS

This is another of the many motions filed by Defendants in the above captioned case. Defendants request that this Court preclude Drs. Calesnick, Barsotti, Zahalsky, Nicholson and Jenkins from offering testimony on behalf of Plaintiffs. All of the Plaintiffs in this case or their decedents are or were residents of the neighborhood adjacent to the Paoli Railyard in Paoli, Pennsylvania. Plaintiffs maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") which were an ingredient of the fire resistant dielectric fluid used in the electrical transformers attached to the underside of the railroad cars which were serviced and maintained in the Yard.

Upon consideration of Defendants' Motion to Preclude the Testimony of Drs. Calesnick, Barsotti, Zahalsky, Nicholson and Jenkins and all responses thereto, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. In their joint pretrial memorandum which was filed July 17, 1992, the Kohn/Klehr Plaintiffs and the Hanes Plaintiffs ("Plaintiffs") named three expert witnesses who were not identified in Plaintiffs' March 1992 Rule 26(b)(4) statements. These expert witnesses were Banjamin Calesnick, M.D. ("Dr. Calesnick"), Deborah Barsotti, Ph.D. ("Dr. Barsotti") and Arthur Zahalsky, Ph.D. ("Dr. Zahalsky").

2. Plaintiffs also named as fact witnesses in their joint pretrial memorandum two scientists who Defendants

argue have no known connection with the facts of this case and appear in reality to be expert witnesses. These proposed fact witnesses are William Nicholson, Ph.D. ("Dr. Nicholson") and Cate Jenkins, Ph.D. ("Dr. Jenkins").

3. On June 4, 1991, this Court entered a scheduling Order which required all Plaintiffs in this case to designate, on or before March 17, 1992, "all trial expert witnesses and provide defendants with the substance of their trial testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4)." This Order required the parties to identify and provide Rule 26(b)(4) statements for all trial experts including those who had previously submitted opinions for the 1988 summary judgment motion.

4. Plaintiffs failed to identify Drs. Calesnick, Barsotti and Zahalsky in accordance with this Court's Order of June 4, 1991. The first time that Defendants had notice of Plaintiffs' intention to call these experts at trial was on July 17, 1992 in Plaintiffs' joint pretrial memorandum. This disclosure was only two weeks from the scheduled trial date in this case of August 3, 1992.

5. Plaintiffs argue that these experts and their anticipated testimony have been well known to Defendants since 1988. However, this argument is not consistent with the fact that even though the Kohn/Klehr Plaintiffs had relied on the opinions of Ian C.T. Nisbet, Ph.D. in 1988, they produced another report from Dr. Nisbet and advised Defendants that they once again planned to proffer his testimony in accordance with this Court's June 4, 1991 Order. In addition, the Hanes Plaintiffs "re-designated" G. John DiGregorio, M.D., Ph.D. as a trial witness and stated that Dr. DiGregorio's opinions were as expressed in his 1988 deposition. Defendants likewise provided Rule 26(b)(4)

Statements for several experts who had rendered opinions in support of its 1988 summary judgment motion.

6. Defendants did not attempt to depose or redepose Drs. Calesnick, Barsotti and Zahalsky during the discovery period since these experts were not identified as trial experts in this case in accordance with this Court's Order. Defendants therefore did not move *in limine* to exclude the testmony of Drs. Calesnick, Barsotti and Zahalsky.

7. Defendants deposed all the purported expert witnesses on exposure and medical causation that were properly identified by Plaintiffs in this case and filed motions *in limine* to exclude the testimony of these experts under Federal Rules of Evidence 702, 703 and 403.

8. Defendants did depose Drs. Barsotti and Zahalsky back in 1988. However, under this Court's June 4, 1991 Order, Defendants were entitled to know by March 17, 1992 who Plaintiffs were calling as experts at trial and to depose or re-depose any of these experts during the expert discovery period.

9. Defendants have never deposed Dr. Calesnick. Dr. Calesnick offered an opinion in support of Plaintiffs' opposition to Defendants' 1988 motion for summary judgment. At that time, Dr. Calesnick submitted an affidavit where he stated that "the Plaintiffs have been exposed to PCBs," and that there was a "potential for them to sustain injuries from PCB exposure." Even Plaintiffs themselves disclaimed that Dr. Calesnick was being designated as a trial expert at that time. *See* Memorandum in support of Plaintiffs' Answer to Defendants' Joint Motion to Strike at 4, Filed September 23, 1988.

10. Dr. Nicholson was identified by Plaintiffs in their joint pretrial memorandum of July 17, 1992 as a "fact witness." Dr. Nicholson is a physicist who works in the Division of Environmental and Occupational Medicine at Mt. Sinai Hospital in New York. In 1988, Dr. Nicholson produced a "meta-analysis" of epidemiological data that

Plaintiffs submitted in support of their opposition to Defendants' 1988 summary judgment motion.

11. Dr. Jenkins was also identified by Plaintiffs in their joint pretrial memorandum of July 17, 1992 as a "fact witness." Dr. Jenkins is an EPA scientist and a purported authority on dioxins. Plaintiffs argue that jurors should be permitted to hear Dr. Jenkins' testimony since her testimony demonstrates the uncertainty that inheres in epidemiologic studies and Defendant Monsanto's disregard of the harms related to PCB-based transformer fluids which contain dioxins.

CONCLUSIONS OF LAW

1. Rule 37(b)(2)(B) of the Federal Rules of Civil Procedure provides that, as a sanction for a party's failure to comply with a discovery order, the court may issue an order "prohibiting that party from introducing designated matters in evidence."

2. The Third Circuit has made clear that preclusion of expert testimony is an appropriate sanction where the party proffering an expert has failed to comply with pretrial orders governing designation of experts or disclosure of expert opinions. *See Hagans v. Henry Weber Aircraft Distributors, Inc.*, 852 F.2d 60, 63-65 (3d Cir. 1988); *Semper v. Santos*, 845 F.2d 1233, 1237-38 (3d Cir. 1988).

3. Where preclusion of expert testimony would be equivalent to a dismissal of the case, the court must evaluate the circumstances pursuant to the six factors set in *Poulis v. State Farm Fire & Casualty Co.*, 747 F.2d 863 (3d Cir. 1984). *See Hagans*, 852 F.2d at 64. The *Poulis* analysis is not applicable to this motion because the preclusion of these recently identified experts is not in itself "tantamount to dismissal." *See id.*

4. Defendants attacked the admissibility of Drs. Barsotti and Zahalsky in 1988. The Third Circuit acknowl-

edged that these attacks were "forceful", however, the court went on to state that the record needed to be developed and the requisite factfinding under Rules 702 and 703 of the Federal Rules of Evidence was necessary. *See In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 859 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991). Thereafter Plaintiffs never identified Drs. Barsotti and Zahalsky as trial experts pursuant to this Court's June 4, 1991 Order. Thus, these experts were not re-deposed and the record required by the Third Circuit was not established. Moreover, Defendants have never deposed Dr. Calesnick regarding his opinions or the methodology that he employed in rendering his opinions.

5. I conclude that Defendants have been severely prejudiced by Plaintiffs' failure to designate these experts in accordance to this Court's June 4, 1991 Order. The claims of all Plaintiffs in this case critically depend upon expert testimony concerning Plaintiffs' exposure to PCBs and the causal connection between this exposure and Plaintiffs' alleged injuries. The Order of this Court recognized the necessity of expert depositions in this case and allowed the parties to depose or re-depose opposing trial experts without further leave of the Court.

6. Since Drs. Barsotti, Zahalsky and Calesnick were never designated as trial experts, Defendants had no reason to depose or re-depose these experts regarding their opinions on Plaintiff. Moreover, Defendants never had an opportunity to challenge these experts' qualifications, methodology or data. Defendants had no knowledge that Plaintiffs intended to call these experts at trial until approximately two weeks before the scheduled trial date of August 3, 1992.

7. Plaintiffs' argument that these experts and their anticipated testimony have been well known to Defendants since 1988 simply fails. If Plaintiffs honestly believed that they did not have to redesignate experts that had previ-

ously proffered testimony in this case prior to the June 4, 1991 Order of this Court, then Plaintiffs would not have redesignated Dr. Nisbet and Dr. DiGregorio. Moreover, if these experts are not precluded, Plaintiffs will be significantly rewarded for their failure to designate these experts since Defendants have not had the opportunity to move *in limine*.

8. Plaintiffs shall not be permitted to proffer new experts on the eve of trial when their properly designated experts face exclusion. I conclude that Drs. Barsotti, Zahalsky and Calesnick must be precluded from testifying as expert witnesses in this case since Plaintiffs have failed to comply with the orders of this Court governing designation of experts and disclosure of expert opinions.

9. No other sanction could remedy the severe prejudice to Defendants. Defendants have been deprived of the opportunity to take discovery or further discovery of these experts' opinions on Plaintiffs and to file motions *in limine* to exclude their testimony. Reopening discovery or permitting these experts to testify without further discovery is not appropriate at this stage of the litigation and does not comport with judicial economy.

10. With respect to Drs. Nicholson and Jenkins, I conclude that these witnesses are expert witnesses not fact witnesses. Dr. Nicholson's testimony was regarded by the Third Circuit in *Paoli* as expert testimony. *See Paoli*, 916 F.2d at 856-59. The Third Circuit in determining the admissibility of Dr. Nicholson's "meta-analysis" reviewed his methodology under Federal Rule of Evidence 702. *Id.* Plaintiffs may not circumvent the procedures established by the Federal Rules and the orders of this Court regarding disclosure and discovery of expert testimony by merely identifying Dr. Nicholson as a "fact witness." In addition, the character of Dr. Jenkins' proposed testimony is not factual. Testimony regarding the uncertainty that inheres in epidemiologic studies is certainly not fact testimony but expert testimony.

11. Thus, since Drs. Nicholson and Jenkins were not properly designated as expert witnesses in this case, they must also be precluded from testifying.

Therefore, I shall enter the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
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Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion to Preclude the Testimony of Drs. Calesnick, Barsotti, Zahalsky, Nicholson

and Jenkins and all responses thereto, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

(4)

Supreme Court, U.S.
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No. 94-1070

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, et al.,
Petitioners,

v.

PATRICIA INGRAM, et al.,
Respondents.

Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Third Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Should the Petition for Certiorari be denied where all Courts of Appeal, including the Third Circuit, recognize that decisions to admit expert testimony are committed to the discretion of the district courts and thus are to be reviewed for an abuse of such discretion?

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INTRODUCTION

Every Circuit Court recognizes that decisions to admit scientific evidence are committed to the discretion of trial courts. Such decisions are to be reviewed, therefore, for an abuse of such discretion. The Petition for Certiorari rests on a fallacy: that some appellate courts review for "abuse of discretion" while others review for "manifest error." As Respondents, Patricia Ingram, et al.[1], demonstrate below, however, these two terms are used interchangeably to describe the same deferential standard of review. Because it raises a mere matter of terminology, not a split among the Circuits on a matter of substance, the Petition should be denied.

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[1] This brief is filed on behalf of two groups of litigants, referred by the court below as the "'Kohn /Klehr' plaintiffs" (John Ingram, Sr. in his own right and for Patricia Ingram, deceased; April Ingram Robinson-Ray; John Ingram, Jr.; Mabel Brown; George Burrell, Priscilla Etheridge Burrell, in their own right and as parents and natural guardians of Amber Shardai Burrell, a minor; Priscilla Etheridge Burrell, as parent and natural guardian of Monica Hilton, a minor; Wallace D. Cummins; K. Louise Jones, in her own right and as Administratrix of the Estate of Harvey N. Jones, Jr., deceased; James Lament; Mary Knight; William Butler; Theresa Butler; Marvin Simpson; Alan Simpson; Karen Simpson; Donald Simpson; Brian Jackson; Bessie Cunningham, in her own right and as representative of Matthew Cunningham) and the "'Hanes' plaintiffs" (Christopher S. and Jacqueline M. Brown; Cathlene Brown; Craig A. Brown; Catherine D. Brown; Mary Retta Johnson; Margherita Barbetta; Celeste Brown, Clemmon L. Brown, Cloyd Brown, and Curtis Brown). *See In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 736 (3d Cir. 1994) (hereafter, *Paoli II*).

COUNTERSTATEMENT OF THE CASE

Petitioners' Statement of the Case contains misstatements and omissions.[2] Respondents adopt by reference the statement of facts in the opinion presented for review and emphasize the following:

1. These consolidated actions were commenced in 1986 on behalf of 38 people who live adjacent to the Paoli Railroad Yard (the "Yard") to recover for personal injuries and property damage caused by polychlorinated biphenyls ("PCBs") and other related transformer fluid toxins, including PCDFs ("furans") and PCDDs ("dioxins"). These chemicals were used, leaked, spilled, and discharged at the Yard for more than thirty years. Most related claims (*i.e.*, those of more than 250 other individuals arising from the same PCB contamination of the Yard) are pending in Pennsylvania state court, *In re Paoli Railroad Yard PCB Litigation*, Civil Action No. 92-08542 (CCP Chester County). A class-wide settlement with one defendant has been approved under Pennsylvania class action rules.

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[2] For example, the Certiorari Petition states (at 3) that Respondents offered the opinions of two physicians and one physicist at the *in limine* hearing. This disregards the testimony of a chemist found to be persuasive by the Third Circuit, *Paoli II*, 35 F.3d at 778, the opinions of a chemical engineer and real estate expert as to whom Petitioners' motions in limine were denied, and the voluminous documentary evidence offered in support of the disputed expert opinions.

2. Virtually every major industrialized nation, including the United States, has banned or severely restricted the manufacture, sale, and use of PCBs.[3] Thus, in this case, it is the conclusions of Petitioners' experts which are at odds with those consistently reached by courts, legislatures, and pertinent administrative agencies. *Cf. Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 1995 U.S. App. LEXIS 12 at *21 n.9 (9th Cir. Jan. 4, 1995) (the FDA continues to approve Bendectin for use by pregnant women and it is still widely used in this fashion abroad).

3. The Paoli Railroad Yard is a part of a notorious Superfund site,[4] once described by the National Institute for Occupational Safety and Health (NIOSH) as having the worst PCB contamination ever encountered during a health

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[3] The Toxic Substances Control Act ("TSCA") focuses primarily on PCBs and bans, *inter alia*, their manufacturer. *See* 15 U.S.C. §2605(e). TSCA was supported by unequivocal findings, such as: "[1] PCBs have been found... to cause severe skin and liver problems in humans.... [and] [2] [t]here is no dispute over their toxicity to wildlife and to humans." 122 Cong. Rec. 8281 (1976). *See also Environmental Defense Fund, v. EPA*, 598 F.2d 62, 65-66, 84 n.78 (D.C. Cir. 1978) (PCBs are extremely toxic to humans and are suspected of causing a significant share of health and ecological problems) (*quoting* the Sixth Annual Report of Council on Environmental Quality 108 (1975)); *accord Matter of Quanta Resources Corp.*, 739 F.2d 912, 913 n.1 (3d Cir. 1984), *cert. granted* 469 U.S. 1207 (1985), *aff'd*, 474 U.S. 494 (1986); *Environmental Defense Fund, Inc. v. EPA*, 636 F.2d 1267, 1270 (D.C. Cir. 1980).

[4] The EPA Site includes the 28 acre railroad yard and the adjacent watershed in which Respondents reside. (A6127).

inspection. (A4046). It is located at the crest of a hill; the Respondents live downgradient from it in the area identified by the Environmental Protection Agency (EPA) as having experienced the most severe PCB runoff. (A6204).

4. In 1992, six years after completing emergency remediation work and almost a decade after PCBs were removed from nearby trains, the EPA determined that PCBs were *still* found at the Yard and Respondents' homes at dangerous levels. Thus, in its July 1992 Record of Decision (ROD) regarding the Paoli Site, the EPA ordered further remedial actions, including: (1) reducing the level of PCBs in soil at the Yard to 25 parts per million ("ppm"), (2) reducing the level of PCBs in residential soils to 2 ppm, (3) erecting new erosion controls to reduce water runoff from the Yard to Respondents' homes, and (4) creating deed restrictions to prohibit any residential or agricultural use of the Yard. (A6123-25). Although EPA submits that these actions, when completed, will reduce "excess cancer risks" to acceptable levels, it acknowledges that hazardous substances will be left on site "above health-based levels." (A6125).

5. In the decision now presented for review, *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994) (hereafter, *Paoli II*), the Third Circuit stated no fewer than **sixteen times** that it would only reverse those decisions of the trial court which constituted an "abuse of discretion." *See infra* §B3. Using this deferential standard, most of the district court's evidentiary

decisions were affirmed. The same cannot be said of the first series of evidentiary rulings (and grants of summary judgment) in these cases. *See In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), *cert. denied*, 499 U.S. 961 (1991) (hereafter, "*Paoli I*").[5]

REASONS FOR DENYING THE WRIT

A. These Actions Are Not Ripe For Review

Because there has not been a final disposition in this matter and it has been remanded for further proceedings, it is not ripe for review by this Court. *See, e.g., Brotherhood of Locomotive Fireman v. Bangor & A.R. Co.*, 389 U.S. 327, 328 (1967); *American Construction Co. v. Jacksonville, T. & K. R. Co.*, 148 U.S. 372, 384 (1893).

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[5] In *Paoli I*, the Third Circuit concluded that the district court abused its discretion repeatedly, first, by failing to conduct an adequate "factual inquiry" into the disputed issues of scientific reliability. *Paoli I*, 916 F.2d at 836, 853. Indeed, the trial judge granted defendants' motions *in limine* without so much as oral argument and then failed to articulate his reasons for doing so. *Id.* Moreover, the district court abused its discretion by insisting on a "certain kind of degree or background" for Respondents' experts, *id.* at 855-56, making "credibility judgments," *id.* at 858, insisting that scientific evidence not "peer reviewed" was inherently unreliable, *id.*, and entering an unduly restrictive "case management order" which, *inter alia*, denied Respondents an opportunity to discover Petitioners' experts' positions. *Id.* at 854.

The Third Circuit has remanded this matter, for a second time, for trial. At trial, some but not all of the expert testimony at issue may be offered, and it may or may not be accepted by the jury. This case, which has already been in suit for almost nine years, thus may be resolved in a number of ways that will render moot the decisions about which Petitioners complain. Moreover, as shown below, no conflict of authority exists which might justify this Court's intervention at this time.

B. No Conflict of Authority Exists To Merit This Court's Review Of The Third Circuit's Decision.

While this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786 (1993), did not comment upon the well-established rule that evidentiary decisions are committed to trial judges' discretion, the Petitioners argue that it has somehow engendered three disparate standards among the Circuits.[6] More particularly, Petitioners argue that in the wake of *Daubert* the First, Second, Fifth, Sixth and Seventh Circuits reverse only for "manifest error." *See* Petition For A Writ of Certiorari at 12-13. Conversely, the Fourth, Eighth, Ninth, Tenth and D.C. Circuits purportedly apply what Petitioners call a "simple" abuse of discretion standard, *id.* at 13, while the Third Circuit, in the decision presented

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[6] Though preceding *Daubert*, Petitioners made the same argument as they do now in their unsuccessful 1990 Certiorari Petition. *See General Electric Co., et al., v. Knight, et al.*, Reply In Support of Petition for a Writ of Certiorari, at 6, No. 90-1309 (Oct. Term 1990) (the Third Circuit failed to apply the so-called "clearly erroneous" standard of review).

for review, applied what Petitioners must regard as a "complex" abuse of discretion standard of review.[7]

As Petitioners must acknowledge, all Circuits recognize that evidentiary decisions are committed to trial judges' discretion. Thus, they are to be reviewed for an abuse of that discretion. *See, e.g., Pierce v. Underwood*, 487 U.S. 552, 558 (1988). Contrary to Petitioners' argument, there is no practical difference between the "abuse of discretion" and "manifest error" terms used to describe the deferential standard of review given trial judges' evidentiary decisions. *See, e.g., Hamling v. United States*, 418 U.S. 87, 108 (1974) ("abuse-of-discretion" standard); *Salem v. United States Lines*, 370 U.S. 31, 35 (1962) ("clearly erroneous" standard); *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1990) (citing *Salem* as requiring an "abuse of discretion" standard), *cert. denied*, 112 S.Ct. 163 (1991).[8] *See*

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[7] Although they do not so state, Petitioners apparently view the so-called "simple" abuse of discretion standard as less deferential than the "manifestly erroneous" standard which they prefer.

[8] Indeed, some opinions define an abuse of discretion as a "clear" or "manifest" error. *E.g., Sage Realty Corp. v. Insurance Co. of North America*, 34 F.3d 124, 128 (2d Cir. 1994) (evidentiary "determinations will not be reversed in the absence of an abuse of discretion amounting to manifest error"); *United States v. Hauert*, 1994 U.S. App. LEXIS 31882 *13 (7th Cir. 1994) (finding "no abuse of discretion, no clear error" in preclusion of lay opinion testimony); *United States v. Pearce*, 912 F.2d 159, 163 (6th Cir. 1990) (admission of expert testimony is reviewed for "abuse of discretion" and sustained unless "clearly erroneous"), *cert. denied*, 498 U.S. 1093 (1991); *National Metal Finishing Co., Inc. v. Barclays American/Commercial, Inc.*, 899 F.2d 119, 123 (1st Cir. 1990) ("abuse of discretion" found if

(continued...)

generally 1 S. Childress & M. Davis, *Standards of Review* §4.2 at 233 (1986) (review of expert testimony decisions for manifest error "appears to work out to an abuse of discretion test").[9] Indeed, as demonstrated below, the "abuse of discretion" and "manifest error" terms are used in all Circuits, often interchangeably, to illustrate that every possible error made by a trial court in admitting or excluding evidence need not be reversed. *See infra* pp. 9, 12, 16-17.[10]

1. The Courts Which Purportedly Apply A "Manifestly Erroneous" Standard Actually Review For An Abuse of Discretion.

Petitioners erroneously argue that the First, Second, Fifth, Sixth and Seventh Circuits review for "manifest

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[8](...continued)
a decision is "clearly erroneous"); *United States v. Ortiz*, 804 F.2d 1161, 1164 n.2 (10th Cir. 1986) ("abuse of discretion" found if decision is "clear error").

[9] *Compare* 22 Wright and Graham, *Federal Practice and Procedure*: Evidence §5166, at 28 (1994 Supp.) (trial judges' evidentiary decisions are reviewed for an "abuse of discretion") *with* 3 *Weinstein's Evidence* ¶702[2], at 702-22 to 702-23 (1994) (trial judges' evidentiary decisions are reviewed for "manifest error").

[10] *See, e.g., Wilson v. City of Chicago*, 6 F.3d 1233, 1238 (7th Cir. 1993) (contrasting simply evidentiary error with an "abuse of discretion"); *cert. denied*, 114 S. Ct. 1844 (1994); *Peteet v. Dow Chemical Co.*, 868 F.2d 1428, 1434 (5th Cir.) (contrasting the admission of expert testimony assumed *arguendo* to have been in error with an evidentiary decision that is "manifestly erroneous"), *cert. denied*, 493 U.S. 935 (1989).

error," not an "abuse of discretion." *See* Petition For A Writ of Certiorari (hereafter, "Petition"), at 12-13.

The first decision which, according to Petitioners, exemplifies the "manifestly erroneous" line of cases is *United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993). Of pertinent concern there was whether the trial court's **concededly erroneous** denial of a motion *in limine* constituted reversible error.[11] In resolving **this** question, the court emphasized that trial judges have "substantial discretion" in connection with the admission of opinion evidence and, thus, their rulings are upheld unless "manifestly erroneous." *Id.* at 1183, *quoting Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962). That *Sepulveda* did not announce a standard of review different from the "abuse of discretion" standard is apparent when one examines the four Fed.R.Evid. 702 cases on which the court relied, *see* 15 F.3d at 1184: (1) *United States v. Angiulo*, 897 F.2d 1169, 1189 (1st Cir.) (the district court did not abuse its discretion in permitting expert testimony as to defendants' roles in a poker operation), *cert. denied*, 498 U.S. 845 (1990); (2) *United States v. Ladd*, 885 F.2d 954, 960 (1st Cir. 1989) (district court "acted well within its discretion" in permitting expert testimony regarding the "idiom and workings of the heroin community"); (3)

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[11] The prosecution in *Sepulveda* sought to introduce the testimony of a police commander with regard to the defendant's intent to distribute drugs. After a related motion *in limine* was denied, the police commander began to testify. Cross-examination revealed, however, that his testimony was highly speculative. Accordingly, the trial court granted a motion to strike his testimony and instructed the jury in language described as "firm, clear, and to the point" to disregard the commander's testimony in its entirety. 5 F.3d at 1182-83.

United States v. Angiulo, 847 F.2d 956, 975 (1st Cir. 1988) (the district court did not "abuse its discretion" in admitting FBI agent's testimony about defendants' relationships with a criminal organization); *cert. denied*, 488 U.S. 852 & 488 U.S. 928 (1988); (4) *United States v. Hoffman*, 832 F.2d 1299, 1310 (1st Cir. 1987) (court did not "abuse [its] discretion" in permitting agent to testify as a DEA expert on the practices and idiom of the cocaine community).[12]

Petitioners' argument that the Second Circuit applies a "manifestly erroneous" standard is based upon *United States v. Daccarett*, 6 F.3d 37 (2d Cir. 1993), *cert. denied sub nom. Creaciones Viviana Ltda. v. United States*, 114 S.Ct. 1294, 1295, 1538 (1994). Primarily concerned with the constitutionality of certain warrantless seizures, this opinion quickly resolved the only evidentiary dispute before it: whether opinion testimony from someone identified only as a fact witness constituted unfair surprise. In response, the Second Circuit simply noted, "Judge Weinstein's determination that this testimony would help the jury was neither 'manifestly erroneous' nor a 'clear abuse of discretion.'" *Id.* at 58. As in the First and every other Circuit, these terms are used interchangeably in the Second Circuit. *See, e.g., United States v. Aminy*, 15

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[12] *See also Williams v. Poulos*, 11 F.3d 271, 282 (1st Cir. 1993) (abuse of discretion is the standard); *United States v. Echeverri*, 982 F.2d 675, 680 (1st Cir. 1993) ("manifest abuse of the trial court's discretion"); *Apostol v. United States*, 838 F.2d 595, 599 (1st Cir. 1988) (finding no "abuse of discretion" after quoting "manifestly erroneous" language from *Salem*); *Forbro Design Corp. v. Raytheon Co.*, 532 F.2d 758, 762 (1st Cir. 1976) (citing *Salem* for the proposition that the appropriate standard of review is an "abuse of discretion").

F.3d 258, 261 (2d Cir. 1994) (trial court's decisions to admit testimony under Fed.R.Evid. 702 will be upheld absent "manifest error or abuse of discretion").[13]

Petitioners' argument that the Fifth Circuit applies a "manifestly erroneous" standard is based upon *Rosado v. Deters*, 5 F.3d 119 (5th Cir.1993), *quoting Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (en banc; applying *Frye*), *cert. denied*, 112 S.Ct. 1280 (1992). While both of these cases contain "manifestly erroneous" language, both applied an abuse of discretion standard of review. *See Rosado*, 5 F.3d at 124 (no "abuse of discretion" in excluding accident reconstructionist's opinion because he could not identify its physical or mathematical bases); *Christophersen*, 939 F.2d at 1115 (trial court had not "abuse[d] its discretion" in excluding unreliable medical testimony).[14]

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[13] *See also United States v. Quiroz*, 13 F.3d 505, 513 (2d Cir. 1993) (no abuse of discretion found in admitting expert report); *Malarkey v. Texaco, Inc.*, 983 F.2d 1204, 1210 (2d Cir. 1993) (a "manifestly erroneous" evidentiary decision *is* an abuse of the trial court's discretion); *United States v. Onumonu*, 967 F.2d 782, 786 (2d Cir. 1992) (reviewing for an abuse of discretion means that "clearly erroneous" evidentiary decisions are to be reversed). *See generally Sage Realty Corp. v. Insurance Co. of North America*, 34 F.3d 124, 128 (2d Cir. 1994) (evidentiary determinations are upheld absent "an abuse of discretion amounting to manifest error").

[14] *See also Carroll v. Morgan*, 17 F.3d 787, 789-90 (5th Cir. 1994) (trial judge's decision to admit expert testimony is reviewed for an abuse of discretion) (*reh'g en banc denied*, 26 F.3d 1117); *Marcel v. Placid Oil Co.*, 11 F.3d 563, 568 (5th Cir. 1994) (same); *Arleth v. Freeport-Moran Oil & Gas Co.*, 2 F.3d 630, 635 (5th Cir. 1993) (same) (*reh'g denied*, 9 F.3d 105). *See generally Davidson Oil*

(continued...)

Petitioners' argument that the Sixth Circuit applies a "manifestly erroneous" standard is based upon *United States v. Bonds*, 12 F.3d 540, 544 (6th Cir. 1993), and *Cantrell v. GAF Corp.*, 999 F.2d 1007, 1014 (6th Cir. 1993), two decisions in which the appellate court was presented with admitted or assumed evidentiary mistakes and therefore emphasized the "manifestly erroneous" language of *Salem*, 370 U.S. at 35. In *Bonds*, DNA evidence had been admitted by the district court under the *Frye* standards that were subsequently rejected in *Daubert*. 12 F.3d at 554-555. The court refused to reverse the underlying criminal conviction because this admittedly irregular evidentiary ruling did not constitute "manifest error." *Id.* at 554. At the same time, the court stated the general rule: "We review the trial court's admission of testimony and other evidence under an abuse of discretion standard." *Id.* Likewise, in *Cantrell*, the court refused to overturn a judgment based in part on a doctor's personal observations linking laryngeal cancer to asbestos. 999 F.2d at 1012-13. Even if this testimony were erroneously admitted, it did not constitute "manifest" error. *Id.* at 1014. At the same time, the standard of review is that a "trial court's exercise of discretion" will not be disturbed. *Id.*[15]

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[14](...continued)
Country Supply v. Klockner, Inc., 908 F.2d 1238, 1245 (5th Cir. 1990).

[15] *See also United States v. Howard*, 1994 U.S. App. LEXIS 31536 (6th Cir. Nov. 8, 1994) (admission of expert testimony "is

(continued...)

Petitioners' argument that the Seventh Circuit applies a "manifestly erroneous" standard of review is based upon *Mars v. United States*, 25 F.3d 1383 (7th Cir. 1994), a personal injury action brought under the Federal Tort Claims Act. The Seventh Circuit affirmed a decision (made by a magistrate judge) that the plaintiff's neck injuries were pre-existing, not suffered in a collision with a postal vehicle. In response to appellant's argument that this finding was based on unreliable expert evidence, Judge Posner clarified the "mistaken dictum" in *Cella v. United States*, 998 F.2d 418, 423 (7th Cir. 1993), which appeared to state that courts of appeal review trial judges' evidentiary decisions *de novo*. *Mars*, 25 F.3d at 1384. Instead, trial judges' evidentiary decisions are not reversed unless "clearly erroneous." *Id.* Pertinent Seventh Circuit jurisprudence equates such an error with an abuse of discretion. *See, e.g., Wilson v. City of Chicago*, 6 F.3d 1233, 1238 (7th Cir. 1993) (per Posner, J.) (new trial warranted because certain evidentiary errors were not "harmless" but, as to others, including medical testimony challenged under *Daubert*, the "judge [did not] abuse[] his discretion"); *cert. denied*, 114 S. Ct. 1844 (1994).[16]

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[15](...continued)
reviewed for abuse of discretion"); *United States v. Nallie*, 1994 U.S. App. LEXIS 230 (6th Cir. Jan. 6, 1994) (same); *Liggons v. Roehm Gmbh*, 1993 U.S. App. LEXIS 1335, *9 (6th Cir. Jan. 20, 1993) (same). *See also United States v. Bolton*, 1994 U.S. App. LEXIS 4888, *6 (6th Cir. March 15, 1994) (describing standard as both "manifest error" and abuse of discretion, holding no such abuse existed).

[16] *See, e.g., Wallace v. Mulholland*, 957 F.2d 333, 336 (7th Cir. 1992) (abuse of discretion review given to decisions to admit or

(continued...)

2. Those Circuits Which The Petition Acknowledges Apply An Abuse of Discretion Standard Also Employ "Manifestly Erroneous" Terminology.

Though Petitioners' recognize that the Fourth, Eight, Ninth, Tenth and District of Columbia Circuits apply an "abuse of discretion" standard of review, they erroneously suggest that this standard conflicts with the decisions reviewed in §1 above. Yet, in each of the following decisions, the court reviewed the admission or exclusion of expert testimony under an "abuse of discretion" standard while also quoting the "manifestly erroneous" language of *Salem v. United States Lines*, 370 U.S. 31, 35 (1962).[17]

In the Fourth Circuit, *see, e.g., United States v. Grandison*, 780 F.2d 425, 433 (4th Cir. 1985); *United States v. MacDonald*, 688 F.2d 224, 228 (4th Cir. 1982), *cert. denied*, 459 U.S. 1103 (1983).

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[16](...continued)
exclude expert testimony). *See also Richardson v. Consolidated Rail Corp.*, 17 F.3d 213, 218 (7th Cir. 1994) (because trial court has broad discretion in admitting expert testimony, its decisions will only be reversed if "manifestly erroneous"; admission of non-expert testimony is likewise reviewed for an abuse of discretion; here, any error in allowing doctors to testify was "harmless").

[17] *See also General Ill. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1409 n.2 (Fed. Cir. 1994) (district court's decision to admit or exclude expert testimony are not disturbed absent an abuse of discretion); *Evans v. Mathis Funeral Home, Inc.*, 996 F.2d 266 (11th Cir. 1993) (same).

In the Eighth Circuit, *see, e.g., United States v. Bartley*, 855 F.2d 547, 551 (8th Cir. 1988); *Wilmington v. J.I. Case Co.*, 793 F.2d 909, 919 (8th Cir. 1986).

In the Ninth Circuit, *see, e.g., United States v Rahm*, 993 F.2d 1405, 1418 (9th Cir. 1993); *Rogers v. Raymark Industries, Inc.* 922 F.2d 1426, 1429, 1431 (9th Cir. 1991).

In the Tenth Circuit, *see, e.g., United States v. Simpson*, 7 F.3d 186, 188 (10th Cir. 1993); *Lutz Farms v. Asgrow Seed Co.*, 948 F.2d 638, 647 (10th Cir. 1991).

In the District of Columbia Circuit, *see, e.g., Coleman v. Parkline Corp.*, 844 F.2d 863, 866 (D.C. Cir. 1988); *United States v. Shorter*, 809 F.2d 54, 57 (D.C. Cir. 1987) *cert. denied*, 484 U.S. 817 (1987). *Cf. Morgan v. District of Columbia*, 824 F.2d 1049, 1069 (D.C. Cir. 1987) (whether expert testimony was required to prove case also is a matter left to court's discretion; it and related decisions are sustained unless "clearly erroneous").

3. As Demonstrated In The Decision Below, The Third Circuit Also Applies An Abuse Of Discretion Standard.

In the decision presented for review, the Third Circuit stated and repeatedly demonstrated that evidentiary decisions are reviewed for an abuse of discretion -- the same standard applied in *all* other circuits. *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 749-50 (3d Cir. 1994). Thus, most of the trial court's determinations were upheld, including some thought to be erroneous. For example, while litigants **should** be permitted to depose

opposing experts who testify at *in limine* hearings, the Third Circuit "conclude[d] that the district court [ha]d not abuse[d] its discretion in allowing experts, who had provided affidavits, to testify at the *in limine* hearing without being deposed." *Id.* at 739. Further, with regard to each of its other holdings under Fed.R.Evid. 403, 702 or 703, the Third Circuit made clear that it was reviewing only for abuses of the trial judge's discretion.[18]

The Third Circuit carefully reviewed the support for, and criticisms of, the opinions of Doctors Sherman and DeGregorio in order to determine whether the district court "abused its discretion" in concluding that their causation methodologies were unreliable. *Id.* at 757-58, 759, 785. Ultimately, the court concluded that the district court had "abused its discretion" in excluding those opinions of these doctors which were based on "standard diagnostic techniques" or which reasonably rebutted defense experts' causation theories. *Id.* at 760. Conversely, "the district court acted within its discretion" in excluding causation opinions thought to be based on litigant self-reporting. *Id.* at 762. The net effect of this explicit "abuse of discretion" standard of review was to *affirm* the exclusion of most of the causation evidence offered in support of Respondents' present bodily injury claims. *Id.* at 766-67, 771.

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[18] *See also DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 944 (3d Cir. 1990) (abuse of discretion is general standard); *Arnold v. Loose*, 352 F.2d 959, 962 (3d Cir. 1965) (trial judge did not "exceed his discretion" or make a "clearly erroneous" evidentiary decision).

Even with regard to the trial judge's inexplicable conclusion that one of the nation's leading PCB experts, Ian C.T. Nisbet, Ph.D.,[19] was unqualified to testify, the Third Circuit "defer[ed] to the district court." *Id.* at 773. Thus, when it considered "whether the district court [had] acted within its discretion," *id.* at 777, in excluding the results of Eco-Logic, a laboratory on whose data Dr. Nisbet had relied,[20] the Third Circuit *observed* that the laboratory's methodology was essentially unchallenged and that one of its chemists had "provided a fairly convincing defense of [its] quality control measures" but *held* that the district court "acted within its discretion" in excluding the laboratory's results. *Id.* at 778. *Cf. Bonds*, 12 F.3d at 554-555 (purported errors by laboratories are generally left for the jury to resolve).

The Third Circuit noted that a similarly close call was presented regarding the admissibility of evidence of furans and dioxins, chemicals undoubtedly present at the

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[19] EPA's PCB effluent standards, 42 Fed. Reg. 6532 (1977), were promulgated and upheld in large part on the basis of Dr. Nisbet's work. *See Environmental Defense*, 598 F.2d at 89 (relying upon the "Criteria Document" prepared by Dr. Nisbet which surveyed, at EPA's request, the scientific literature on PCBs). Like the EPA and the D.C. Circuit, the Third Circuit has recognized Dr. Nisbet to be "an extremely well qualified" expert. *Paoli II*, 35 F.3d at 774; *see also id.* at 771. Nevertheless, the district court "provide[d] *no* justification" for excluding the vast majority of Dr. Nisbet's opinions. *Id.* at 778 (emphasis added).

[20] The EPA also relies upon Eco-Logic to do PCB-related work and has engaged it to provide Bay City, Michigan with a thermochemical reactor designed to incinerate PCBs. *See The Philadelphia Inquirer*, Oct. 6, 1992 at F1.

Paoli Railroad Yard and indisputably created when PCBs are over-heated. (A4020). Nevertheless, the Third Circuit held "that the district court acted within its discretion in excluding this evidence under [Fed.R.Evid.] 403." *Paoli II*, 717 F.3d at 783.

Likewise, the Third Circuit upheld the district court's exclusion of two human poisoning episodes involving PCBs (the Yusho and Yu Cheng incidents) "as substantive evidence," *id.* at 765, even though it noted that one of the Petitioners' experts has testified that the Yusho incident was among "the biggest developments" in the history of the scientific investigation of PCBs. *Id.* at 784. More particularly, the Third Circuit "h[e]ld that the district court was within its discretion" in excluding this clearly relevant evidence under Fed.R.Evid. 403. *Id.* at 784.

The Third Circuit also instructed, as have other Circuits since *Daubert*[21], that while deferential, the abuse of discretion standard of review is not toothless. Indeed, particularly when they are based on a scientific record that may be reviewed on appeal as readily as by the trial judge, and when they are tantamount to grants of summary judgment, evidentiary exclusions must be carefully scrutinized (*i.e.*, given a "hard look") so as to guard against the types of abuses of discretion which the trial court has repeatedly committed in this matter. 35 F.3d at

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[21] *See Daubert v. Merrell Dow Pharmaceuticals*, 1995 U.S. App. LEXIS 12, at *8 (9th Cir. Jan. 4, 1995) (abuse of discretion standard is to be applied).

733, 750.[22] Such a prudent guideline is to be expected from Judge Becker. It is praiseworthy, not "certworthy."

Petitioners' failure to acknowledge the Third Circuit's *repeated* references to the Third Circuit's "abuse of discretion" standard is troublesome. Petitioners have either misrepresented the decision below or mean to assert that the Third Circuit simply did *not* do what it repeatedly stated it was doing, *i.e.*, reverse those trial court decisions which constituted an abuse of discretion. In order to test this latter assertion, it would be necessary for this Court to repeat the detailed review of scientific testimony ably conducted by the Third Circuit.[23] The result of this time-consuming process would be unjustifiable delay and an entirely fact-bound opinion.

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[22] Carefully reviewing for an abuse of discretion is completely consistent with many comparable decisions. *See, e.g., Simon v. Shearson Lehman Bros.*, 895 F.2d 1304, 1310 (11th Cir. 1990); *EEOC v. State of Delaware DHSS*, 865 F.2d 1408, 1413 (3d Cir. 1988); *Kearns v. Keystone Shipping Co.*, 863 F.2d 177, 179 (1st Cir. 1988); *Rosenfield v. Wellington Leisure Prods.*, 827 F.2d 1493, 1498 (11th Cir. 1987); *deMars v. Equitable Life Assur. Soc. of U.S.*, 610 F.2d 55, 64-65 (1st Cir. 1979); *Grove v. Dun & Bradstreet, Inc.*, 438 F.2d 433, 438 (3d Cir.), *cert. denied*, 404 U.S. 8981 (1971).

[23] Thus, while it purports to relate to a single legal issue, most of the content of the instant Certiorari Petition is devoted to Petitioners' novel views about the harmfulness of PCBs, and the competence of any expert who would dare to voice a contrary opinion.

This Court's opinion in *Daubert* is not yet two years old. Although there is, as we have shown, no conflict among the Circuits on the appropriate standard of review to apply to district courts' decisions excluding scientific expert testimony, it would in any event be too early for this Court to grant certiorari to resolve any such incipient conflict, even if there were one. The better course would be for this Court to allow the Circuits adequate time and experience in applying *Daubert* in a variety of factual settings. If a true conflict does develop after such experience, there will be no shortage of suitable opportunities for the Court to grant review to resolve it.

CONCLUSION

The Petition for Writ of Certiorari should be denied.

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DATED: January 13, 1995

IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, et al.
Petitioners,

v.

PATRICIA INGRAM, et al.,
Respondents.

Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Third Circuit

PETITION FOR A WRIT OF CERTIORARI

CERTIFICATE OF SERVICE

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OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,
v.
PATRICIA INGRAM, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF FOR ALUMINUM COMPANY OF AMERICA, AMGEN INC., EASTMAN KODAK COMPANY, EXXON COMPANY, U.S.A. (A DIVISION OF EXXON CORPORATION), GENENTECH, INC., JOHNSON & JOHNSON, MERCK & CO., INC., THE PROCTER & GAMBLE CO., THE SHERWIN-WILLIAMS COMPANY, AND USX CORPORATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

If a district court excludes scientific expert testimony as unreliable under the Federal Rules of Evidence as clarified by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, —— U.S. ——, 113 S. Ct. 2786 (1993), is it proper for a reviewing appellate court to apply (as the Third Circuit did in this case) a stringent "hard look" standard that amounts to virtual *de novo* review?

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OCTOBER TERM, 1994

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BRIEF FOR ALUMINUM COMPANY OF AMERICA, AMGEN INC., EASTMAN KODAK COMPANY, EXXON COMPANY, U.S.A. (A DIVISION OF EXXON CORPORATION), GENENTECH, INC., JOHNSON & JOHNSON, MERCK & CO., INC., THE PROCTER & GAMBLE CO., THE SHERWIN-WILLIAMS COMPANY, AND USX CORPORATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

Amici curiae respectfully pray that this Court grant Petitioners' Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit. *Amici* have obtained consent from all parties to file this *amicus* brief. Correspondence evidencing consent has been provided to the Clerk of this Court.[1]

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[1] Petitioners are General Electric Company, National Railroad Passenger Corporation, the City of Philadelphia, Southeastern

INTEREST OF *AMICI CURIAE*

Amici are ten American companies engaged in a wide variety of industrial activities. They include manufacturers of steel, pharmaceuticals, soaps and detergents, petroleum products, imaging equipment and supplies, chemicals, paints and coatings, consumer goods, aluminum, and other products that are a large and vital part of our national economy. The names of most of the *amici* have long been familiar to virtually all Americans. Also included, however, are Amgen Inc. and Genentech, Inc., two relatively new companies that are leaders in using innovative genetic engineering technology to produce pharmaceuticals.

Collectively, *amici* represent the backbone of American industry, both now and for the future. Their total sales in 1993 amounted to well over $100 billion, and during the course of their various histories they have applied for tens of thousands of patents.

All of these companies face the threat of speculative litigation based on expert scientific testimony that falls far short of the standards scientists themselves use in evaluating the validity of their work, and this threat has serious consequences. When "science" for courtroom purposes diverges from scientific methods and principles, companies sometimes pay for injuries or damages they did not cause. Their customers pay too; prices go up and

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Pennsylvania Transportation Authority, Monsanto Company, American Premier Underwriters, Inc., and the Budd Company. Respondents are Westinghouse Electric Corporation, Mabel Brown, George Burrell, Priscilla Burrell, Amber Burrell, Monica Hilton, Wallace D. Cummins, K. Louise Jones, Harvey Jones, James Lament, Christopher Brown, Jacqueline Michelle Brown, Cathlene Brown, Craig Brown, Margherita Barbetta, Mary Retta Johnson, Celeste Brown, Clemmon Brown, Cloyd Brown, Curtis Brown, John Ingram, Sr., John Ingram, Jr., Patricia Ingram, April Ingram Robinson-Ray, Mary Alice Knight, William Butler, Theresa Butler, Bryan Jackson, Allen Simpson, Donald Simpson, Karen Simpson, Marvin Simpson, Matthew Cunningham, and Bessie Cunningham.

some products are never developed or never brought to market.

Like countless other American companies, *amici* must try to make rational business decisions knowing full well that irrational and unpredictable litigation may result. When plaintiffs find experts willing to testify in court about conclusions their scientific colleagues would quickly reject as unfounded and unsupported, juries may reach verdicts completely at odds with reality. Even if jurors sometimes do see through the charade, it is unreasonable and unfair to put companies through the cost of defending claims that are so speculative. The solution, recognized by this Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, —— U.S. ——, 113 S. Ct. 2786 (1993), is for trial judges to review scientific expert testimony carefully and to exclude it when it is unreliable.

Amici are concerned about this case because the Third Circuit has announced a new "hard look" standard of review that discourages district courts from following this Court's mandate in *Daubert* to review and control disputed expert testimony. The Third Circuit's standard amounts to virtual *de novo* review, but it applies only if the trial court excludes expert evidence. Because this one-way "hard look" is at odds with *Daubert*, this case affords an important opportunity to reinforce *Daubert*'s message that federal trial judges must act as gatekeepers to assure both the reliability and relevancy of expert evidence, and to make clear that when a judge conducts detailed evidentiary hearings and explains his or her ruling, a decision to exclude this kind of evidence should be reversed only if manifestly erroneous.

STATEMENT OF THE CASE

The Plaintiffs (here Respondents) in this case lived near a railroad yard located in Paoli, Pennsylvania, a few miles west of Philadelphia. They claimed they had been exposed to PCBs (polychlorinated biphenyls) from the yard, and that this exposure had caused a variety of

physical ailments, and/or had increased their risk of disease.

As explained in detail by the Petitioners in their Petition for a Writ of Certiorari, in 1988 the District Court held the Respondents' expert testimony inadmissible and granted the Petitioners' motion for summary judgment. *In re Paoli R.R. Yard PCB Litig.*, 706 F. Supp. 358 (E.D. Pa. 1988). The Third Circuit reversed and remanded to the District Court with instructions to review scientific evidence issues in greater depth, and to explain more fully its rulings on these issues. *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829 (3rd Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 499 U.S. 961, 111 S. Ct. 1584 (1991).

On remand, the trial judge followed the Appellate Court's instructions by conducting extensive hearings on the disputed evidence. In several unpublished but exhaustively detailed opinions the District Court again held this evidence inadmissible and again granted summary judgment.[2] Despite this thorough evaluation and analysis by the trial judge, the Appellate Court undertook a virtual *de novo* review and reversed several of his evidentiary rulings. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994).[3] To justify this extensive reanalysis of the excluded evidence the Third Circuit created a new "hard look" standard, which is unique not only because of the more stringent review it entails, but also because it applies only if expert evidence is excluded. *Id.* at 750.

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[2] These opinions are reprinted in Part II of the Appendix filed by Petitioners with their Petition for a Writ of Certiorari.

[3] The Third Circuit's opinion in the Federal Reporter is almost 70 pages long. More than half of it is devoted to a detailed expert by expert review of the scientific evidence. The exhaustive preliminary review conducted by the trial court on remand was not criticized in any way as improper or inadequate. The Court of Appeals did not disagree with the procedure or scope of the evidentiary hearing, but focused instead on a number of the factual conclusions the District Court reached about the testimony that was presented.

SUMMARY OF ARGUMENT

The Third Circuit's one-way "hard look" is at odds with this Court's mandate in *Daubert* that district judges act as evidentiary gatekeepers to assure the reliability, relevancy and helpfulness of expert scientific evidence. *Daubert* specifies that to accomplish this task trial judges must undertake a preliminary assessment of whether the reasoning or methodology underlying an expert's testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts at issue.

This Court's opinion in *Daubert* implicitly but clearly recognizes that trial judges are in the best position to make well-informed evaluations of scientific evidence and to determine its admissibility. The message that district judges must review and control expert testimony is unambiguous, and judges have heeded it in the vast majority of post-*Daubert* cases. Virtual *de novo* appellate reexamination after a proper preliminary review by a trial court will only discourage further progress in putting *Daubert* into practice.

The "hard look" conflicts not only with *Daubert*, but with the standard of review applied by every other Circuit that has addressed the admissibility of expert evidence since this Court's decision in *Daubert*. The Appellate Court's opinion in this case also conflicts with long-standing precedent from this Court favoring the "manifestly erroneous" standard for appellate review of trial court rulings on the admissibility of such evidence, and with the widely held view, predating *Daubert*, that a trial court is in a better position to gauge the quality of expert testimony than an appellate court. If a trial court conducts a proper review of expert evidence, as the District Court did in this case, its ruling should be reversed only if manifestly erroneous.

REASONS FOR GRANTING THE PETITION

I. THE THIRD CIRCUIT'S "HARD LOOK" STANDARD CONFLICTS WITH THIS COURT'S RULING IN *DAUBERT*.

The one-way "hard look" conflicts with this Court's mandate in *Daubert* that trial judges must assure the reliability, relevancy and helpfulness of expert evidence. The Third Circuit's concern that trial judges might misunderstand the reliability standard of Fed. R. Evid. 702 and 703 essentially ignores *Daubert's* clarification of these rules and the role of trial judges in applying them. The Third Circuit's concern is further belied by numerous post-*Daubert* district and appellate court opinions indicating that federal judges generally understand this Court's ruling very well. More information has been brought to bear in deciding the admissibility of disputed expert testimony, and more informed decisions have resulted.

A. *Daubert* Requires Trial Courts to Review Disputed Scientific Evidence to Assure That It Constitutes Valid and Relevant Scientific Knowledge.

Daubert's central teaching is the almost tautologically simple rule that when an expert testifies about science, his or her testimony must in fact constitute valid scientific knowledge that is relevant to the case at hand. This requirement is found in Rule 702, which allows expert opinion testimony only when it pertains to "scientific, technical, or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert* makes clear that "[t]he adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' denotes more than subjective belief or unsupported speculation."[4] Requiring "that an expert's testimony per-

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[4] *Daubert*, 113 S. Ct. at 2795.

tain to 'scientific knowledge' establishes a standard of evidentiary reliability." [5]

Daubert further teaches that in accordance with Rule 104(a), trial court's are to determine "at the outset" whether an expert is proposing to testify about scientific knowledge that will assist the trier of fact,[6] and it teaches that trial judges are to serve as gatekeepers in accomplishing this task.[7] Neither the *Daubert* standard nor the obligation of courts to apply it is ambiguous. *Daubert* also explicitly approves the application of Rule 403 to control otherwise admissible evidence that might cause undue delay or confusion if presented to a jury.[8]

This analytical framework clearly places the burden of implementation on trial courts. It is based on the premise that the law "must resolve disputes finally and quickly," [9] and it anticipates and accepts the consequences that exclusion "on occasion will prevent the jury from learning of authentic insights and innovations. That . . . is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." [10]

B. Federal Courts Should Not Be Discouraged from Continuing the Progress They Have Made Under *Daubert*.

Published decisions demonstrate overwhelmingly that district courts understand *Daubert's* mandate, and that they know how to put it into practice. They have responded by conducting more in-depth and detailed evaluations of disputed expert testimony. *See, e.g., Chikovsky v.*

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[5] *Id.*

[6] *Id.* at 2796.

[7] *Id.* at 2798.

[8] *Id.*

[9] *Id.*

[10] *Id.* at 2799.

Ortho Pharmaceutical Corp., 832 F. Supp. 341 (S.D. Fla. 1993) (excluding testimony linking mother's use of acne medication to daughter's birth defects because this conclusion was unsupported by data or published studies); *Virgin Islands v. Penn*, 838 F. Supp. 1054 (D. V.I. 1993) (DNA evidence admitted in rape case after court conducted thorough review of a variety of scientific issues); *Gier v. Educational Serv. Unit No. 16*, 845 F. Supp. 1342 (D. Neb. 1994) (limiting expert psychiatric and psychological testimony because experts had relied on standardized checklists that were not valid for the plaintiffs, who were retarded); *Joiner v. General Elec. Co.*, 864 F. Supp. 1310 (N.D. Ga. 1994) (plaintiffs' expert testimony on causal link between lung cancer and exposure to PCBs excluded); *Hein v. Merck & Co., Inc.*, —— F. Supp. ——, 1994 WL 661834 (M.D. Tenn. 1994) (carefully reviewing testimony of expert on hedonic damages and excluding it after considering factors listed in *Daubert* as well as other factors). *Cf. Meyerhoff v. Michelin Tire Corp.*, 852 F. Supp. 933 (D. Kan. 1994) (holding expert testimony about a warning label was insufficient to prove the label was inadequate); *Richardson v. United States*, 835 F. Supp. 1236 (E.D. Wash. 1993) (in a non-jury case the court ruled that neither party's expert testimony on accident reconstruction had been of any assistance).

This Court's message on gatekeeping was clear, and it has been understood. District courts have begun to conduct "*Daubert* hearings,"[11] and to use a number of available tools in innovative ways to improve their ability to address scientific issues.[12] Hearings and other proce-

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[11] *E.g. Gier v. Educational Serv. Unit No. 16*, 845 F. Supp. 1342 (D. Neb. 1994). *See also* Klein, *The Revolution in Practice and Procedure:* "Daubert *Hearings*", 1 Shepard's Expert & Sci. Evidence Q. 655 (1994).

[12] *See generally* Black et al., *Science and the Law in the Wake of* Daubert: *A New Search for Scientific Knowledge*, 72 Tex. L. Rev. 715, 786-802 (1994).

dures for enhancing the knowledge of trial judges take time, but "on balance, they will save time . . . [and] promote judicial economy." [13] These improvements will quickly come to naught, however, if appellate courts undertake virtual *de novo* review, as the Third Circuit did in this case.

Federal appellate opinions that have addressed district court *Daubert* rulings support the proposition that if a proper preliminary hearing is conducted, a trial court's ruling should be reversed only if manifestly erroneous. *See, e.g., Bradley v. Brown,* —— F.3d ——, 1994 WL 696303 (7th Cir. 1994), a pesticide exposure toxic tort case in which the Seventh Circuit affirmed a ruling excluding expert medical testimony about multiple chemical sensitivity disorder. Having concluded that the trial court had followed the framework set forth in *Daubert,* the appellate court in *Bradley* reviewed its factual findings only to determine if they were manifestly erroneous.

The Third Circuit's "hard look" is thus diametrically at odds with *Daubert* and with the way in which other courts have applied *Daubert.* It defies logic and common sense for a trial court to be put through the painstaking effort that *Daubert* requires only to face being second-guessed if the judge decides to exclude the evidence at issue. It is also manifestly unfair to defendants to force them to prove inadmissibility a second time, and in a forum where it is more difficult to present all the facts bearing on this issue.

Appellate courts, which do not have the benefit of all the information available to trial judges, should not rush to reverse detailed factual findings, nor should they deter exclusion of expert testimony with the threat of a special "hard look" standard of review applicable only if the evidence is excluded. If allowed to stand, the Third Cir-

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[13] Klein, *supra* note 11 at 660.

cuit's one-way "hard look" approach will only undermine this Court's ruling in *Daubert* and discourage trial judges from continuing to follow its mandate to act as gatekeepers.

II. THE THIRD CIRCUIT'S "HARD LOOK" STANDARD CONFLICTS WITH EVERY OTHER CIRCUIT THAT HAS ADDRESSED EXPERT TESTIMONY UNDER *DAUBERT* AND WITH PRE-*DAUBERT* PRECEDENT.

The "hard look" standard of review applied by the Third Circuit to the District Court's evidentiary rulings in this case puts it at odds with every other Circuit that has considered the issue since *Daubert*. The "hard look" is also at odds with this Court's pre-*Daubert* guidance for appellate review of rulings on the admissibility of expert evidence, and with the accepted common sense rule that when a trial court properly considers the issue of admissibility, extensive appellate review is not required.

A. The "Hard Look" Standard Conflicts with Other Circuits' Post-*Daubert* Rulings.

This Court's decision in *Daubert* clarifies the Federal Rules of Evidence that govern expert testimony, but does not expressly address the standard for appellate courts to apply when reviewing district court rulings on the admissibility of such evidence. In the year and a half since *Daubert*, however, eleven Circuits have addressed this issue,[14] and except for the Third Circuit they have all continued to apply either the "manifestly erroneous" or the "abuse of discretion" standard.[15]

The Fifth Circuit, for example, has held that "[a] trial court's ruling regarding admissibility of expert testimony

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[14] As yet there is no decision on point from either the Federal Circuit or the Eleventh Circuit.

[15] Petitioners discuss this issue in detail in their Petition for a Writ of Certiorari, at 12-15.

is protected by an ambit of discretion and must be sustained unless *manifestly erroneous.*" *Rosado v. Deters,* 5 F.3d 119, 124 (5th Cir. 1993) (emphasis added), *quoting Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir. 1991), *cert. denied,* —— U.S. ——, 112 S. Ct. 1280 (1992). The trial court in *Rosado* had refused to allow the plaintiffs' accident reconstruction expert to testify, and the Fifth Circuit affirmed, citing *Daubert* for the proposition that Rule 702 clearly contemplates regulation of expert evidence. *Id.* at 124 n.9; *accord, United States v. McCaskey,* 9 F.3d 368, 379-80 (5th Cir. 1993), *cert. denied* —— U.S. ——, 114 S. Ct. 1565 (1994) (holding that sentencing court's acceptance of expert testimony on composition of cocaine found in defendant's possession was not clearly erroneous).

A number of cases from the Ninth Circuit illustrate the "abuse of discretion" standard. In *United States v. Jones,* 24 F.3d 1177 (9th Cir. 1994), for example, the Court followed this rule (and *Daubert*) in affirming the trial judge's rejection of the defendant's expert voice identification evidence. *See also United States v. Quinn,* 18 F.3d 1461, 1464-65 (9th Cir.), *cert. denied,* —— U.S. ——, 114 S. Ct. 2755 (1994) (citing *Daubert* and applying "abuse of discretion" standard in affirming acceptance of photogrammetry evidence); *United States v. Rincon,* 28 F.3d 921, 923-26 (9th Cir.), *cert. denied,* —— U.S. ——, 115 S. Ct. 605 (1994) (citing *Daubert* and applying "abuse of discretion" standard in affirming rejection of expert testimony concerning the reliability of eyewitness identifications).[16]

Only the Third Circuit has deviated from the approach traditionally taken by federal appellate courts in reviewing

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[16] *See also Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 500-502 (9th Cir. 1994) (applying "manifestly erroneous" standard and citing *Daubert* in affirming trial court's rejection of expert affidavits offered in opposition to summary judgment in a chemical exposure toxic tort case).

a trial court's rulings on the admissibility of expert testimony. Its one-way "hard look" rule is contrary to at least ten other Circuits' post-*Daubert* holdings. It is also contrary to pre-*Daubert* precedent.

B. The "Hard Look" Standard Conflicts with Pre-*Daubert* Precedent.

In cases preceding *Daubert* this Court established that a trial judge's decision to admit or exclude expert evidence "is to be sustained unless manifestly erroneous." *Salem v. United States Lines Co.*, 370 U.S. 31, 35, 82 S. Ct. 1119 (1962). The *Salem* opinion cited with approval to *Spring Co. v. Edgar*, 99 U.S. 645, 658 (1879), which held that

> Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.

Indeed, most pre-*Daubert* courts took this approach, and for good reasons that *Daubert* reinforces. As Judge Weinstein and Professor Berger have stated in their treatise, decisions about the admissibility of expert testimony require detailed, case-by-case analysis, and trial judges therefore must be accorded broad discretion in deciding to admit or exclude it. 3 J. Weinstein & M. Berger, WEINSTEIN'S EVIDENCE ¶ 702(2) at 22-23 (1993). If a court undertakes a proper review, its ruling on admissibility should be reversed only if manifestly erroneous. *See, e.g., In re Air Crash Disaster at New Orleans, Louisiana*, 795 F.2d 1230, 1233 (5th Cir. 1986) (manifestly erroneous standard reflects the superior opportunity of the trial judge to evaluate expert competence and helpfulness of testimony).

Daubert, which specifically mandates more detailed trial court review of disputed expert evidence than in the past, can hardly be understood as having reduced the discretion accorded trial judges. Precedent, both before and

since *Daubert*, thus supports review of evidentiary rulings under the manifestly erroneous standard. The Third Circuit's "hard look" is contrary to long-standing precedent, contrary to *Daubert*, and contrary to the decisions of other circuits that have applied *Daubert*.

CONCLUSION

For the foregoing reasons, *amici* urge this Court to review the Third Circuit's "hard look" heightened scrutiny standard, and to uphold the broad authority and discretion of trial courts to exclude putatively scientific evidence that does not accord with the standards used by scientists to determine scientific validity.

Respectfully submitted,

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

PATRICIA INGRAM, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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REPLY IN SUPPORT OF PETITION FOR CERTIORARI

I.

The brief in opposition highlights the confusion among the courts of appeals as to the proper standard for reviewing trial-court rulings under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993). Respondents acknowledge that other Circuits apply a deferential standard of review, some of them using "abuse of discretion," others reversing only if the trial court's ruling is "manifestly erroneous;" [1] respondents also recognize that in contrast the Third Circuit now holds that "evidentiary exclusions must be carefully scrutinized (*i.e.*, given a 'hard

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[1] "Manifestly erroneous" implies "clearly erroneous," but has also been described as "perhaps . . . a middle position between abuse of discretion review and clearly erroneous review." 2 S. CHILDRESS & M. DAVIS, STANDARDS OF REVIEW 93 (1986).

look')." Br. Opp. 18. Whichever of the former two standards is correct, it is clear that the Third Circuit has adopted a new standard that is different from either, and far less deferential.

Respondents' argument appears to be that it makes no difference—that one standard is about the same as another. But this Court has recognized dozens of times that the standard by which a trial court's ruling is to be reviewed is of fundamental importance to the appellate process. "[T]he standard chosen often affects the outcome of the case." *United States* v. *Vontsteen*, 950 F.2d 1086, 1091 (5th Cir. 1992) (*en banc*). See also *Salve Regina College* v. *Russell*, 499 U.S. 225, 236 (1991); *cf.* Fed. R. App. P. 28(a)(5) (amended Apr. 22, 1993 to require all appellate briefs to "include for each issue a statement of the applicable standard of review"). Certiorari has repeatedly been granted when conflicts as to the standard of appellate review arise. See, *e.g.*, *Salve Regina College* v. *Russell, supra*, 499 U.S. at 233; *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 401 (1990); *Pierce* v. *Underwood*, 487 U.S. 552, 558 & n.1 (1988).[2] The need to settle the standard of review is particularly clear because *Daubert* now is applied so often.

Respondents also pretend that the Third Circuit's new standard is just ordinary "abuse of discretion." But the Court of Appeals took pains here to emphasize that it is not. The Third Circuit explained as clearly as it could that after *Daubert*, if exclusion leads to summary judgment, the Third Circuit will *not* apply a deferential standard—that instead it has adopted, unlike any other Circuit, what it calls "a hard look at (more stringent review of) the district court's exercise of discretion." P.C.A. 52a, P.C. Addendum A6; see also P.C.A. 15a, P.C. Addendum

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[2] See also *Wilton* v. *Seven Falls Co.*, No. 94-562, 63 U.S.L. WEEK 3420 (*cert. granted* Nov. 28, 1994); *First Options of Chicago, Inc.* v. *Kaplan*, No. 94-560, 63 U.S.L. WEEK 3436 (*cert. granted* Dec. 5, 1994).

A3 ("we conclude that the review requires a 'hard look' "). That plainly is not the standard used in other Circuits. The Third Circuit explicitly intended it to be different, and took the trouble to state the reasons why it believed that *Daubert* justified the departure. See P.C.A. 15a, 51a-53a, P.C. Addendum A3, A5-A8.[3]

II.

Since the filing of the petition for certiorari, three decisions that further support review have been reported:

1. In *Tome* v. *United States*, No. 93-6892, 63 U.S.L. WEEK 4046, decided January 10, 1995, this Court two weeks ago held that Federal Rule of Evidence 801(d)(1)(B) was not to be read as altering a previous common-law rule when the Advisory Committee notes showed no intention to do so, 63 U.S.L. WEEK at 4050 (Kennedy, J., for plurality), and "[i]t is well established that 'the body of common law knowledge' must be 'a source of guidance' in our interpretation of the Rules," *id.* at 4052 (Scalia, J., concurring in part and concurring in the judgment).[4] The Third Circuit's reliance on *Daubert*

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[3] Respondents also argue that a decision of a court of appeals reversing a summary judgment and remanding for trial is not ripe for review in this Court. Br. Opp. 5. The cases respondents cite do not remotely support that proposition, and of course this Court reviews such decisions regularly. See, *e.g.*, *Consolidated Rail Corp.* v. *Gottshall*, 114 S. Ct. 2396, 2402 (1994); *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986) ("[b]ecause the Court of Appeals did not apply the correct standard in reviewing [and reversing] the District Court's grant of summary judgment, we vacate its decision and remand"); *Celotex Corp.* v. *Catrett*, 477 U.S. 317 (1986) (same); *Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574, 582 (1986) ("[w]e granted certiorari to determine (1) whether the Court of Appeals applied the proper standards in evaluating [and reversing] the District Court's decision to grant petitioners' motion for summary judgment").

[4] Quoting in part *Daubert*, *supra*, 113 S. Ct. at 2794 (some internal quotation marks omitted), which in turn quoted *United States* v. *Abel*, 469 U.S. 45, 52 (1984), which quoted Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 NEB. L. REV. 908, 915 (1978).

to conclude that the Federal Rules of Evidence by implication altered the previous "manifestly erroneous" standard of *Salem* v. *United States Lines Co.*, 370 U.S. 31 (1962), is inconsistent with that portion of the reasoning in *Tome*. Moreover, the Court of Appeals' detailed second-guessing of the trial court's ruling conflicts with the rule of broad trial-court discretion under Rule 403 which the dissent in *Tome* reiterated, and which other Circuits apply to Rule 702 and 703 rulings as well.[5]

2. Although respondents appear to question whether the Seventh Circuit applies the "manifestly erroneous" standard after *Daubert*, see Br. Opp. 13, that it indeed does so was reconfirmed in *Bradley* v. *Brown*, 1994 U.S. App. Lexis 34763 (7th Cir. Dec. 13, 1994), which explained:

> "We first undertake a *de novo* review of whether the district court properly followed the framework set forth in *Daubert*. See *Mars* v. *United States*, 25 F.3d 1383, 1383-84 (7th Cir. 1994). Provided the district court adhered to *Daubert*'s parameters, we will not disturb the district court's findings unless they are manifestly erroneous."

1994 U.S. App. Lexis 34763 at *6.

3. Continuing the conflict, earlier this month the Ninth Circuit on remand of *Daubert* reaffirmed that in that Circuit rulings under Rules 403 and 702 will "be reviewed under the deferential abuse of discretion standard." *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 1995 U.S. App. Lexis 12 at *8 (9th Cir. Jan. 4, 1995).

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[5] The dissent in *Tome*, while concluding that the Federal Rule there in question did alter the preexisting rule, also cited *Daubert* and quoted this Court's admonition in *United States* v. *Abel*, 469 U.S. 45, 54 (1984), that under Rule 403 "[a] district court is accorded a wide discretion in . . . [a]ssessing the probative value of [proffered evidence], and weighing any factors counseling against admissibility." 63 U.S.L. WEEK at 4053 (Breyer, J., dissenting). The Court of Appeals here used its "hard look" "more stringent review" to reverse rulings based on Rule 403 as well as Rule 702 and 703. See Pet. Cert. 9-10.

III.

Respondents incorrectly assert that "it would be necessary for this Court to repeat the detailed review of scientific testimony ably conducted by the Third Circuit." Br. Opp. 19 (footnote omitted). Far from it. The petition seeks review of a single issue, the standard of review. If the Third Circuit's new standard is correct, then the decision would be affirmed. If it is incorrect, then the case could be remanded for the Court of Appeals to review the trial-court rulings under the correct standard. Review does not require this Court to do any more than decide the proper appellate standard under *Daubert*.[6]

CONCLUSION

For the reasons stated herein and in the petition, certiorari should be granted.

Respectfully submitted,

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[6] Similarly, in *Daubert* itself this Court did not examine the admissibility of particular opinions, but rather resolved the proper standard for district courts to use under Rule 702 and then remanded for appropriate proceedings. 113 S. Ct. at 2799. *Cf.* also *Tome* v. *United States*, *supra*: "[w]e intimate no view . . . concerning the admissibility of any of A. T.'s out-of-court statements . . . . These matters, and others, are for the Court of Appeals to decide in the first instance." 63 U.S.L. WEEK at 4051.

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